

Christina Pramudji, M.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., ) MASTER FILE NO.  
PELVIC REPAIR SYSTEM ) 2:12-MD-02327  
PRODUCTS LIABILITY )  
LITIGATION ) JOSEPH R. GOODWIN  
----- ) U.S. DISTRICT JUDGE  
THIS DOCUMENT RELATES TO )  
THE FOLLOWING CASES IN WAVE 1 OF MDL 200:)  
Joy Essman )  
Case No. 2:12-cv-00277 )  
 )  
Barbara A. Hill )  
Case No. 2:12-cv-00806 ) ORAL DEPOSITION OF  
 ) CHRISTINA PRAMUDJI, M.D.  
Paula Kriz )  
Case No. 2:12-cv-00938 ) MARCH 24, 2016  
 )  
Brenda Riddell )  
Case No. 2:12-cv-00547 )  
 )  
Sharon Carpenter )  
Case No. 2:12-cv-00554 )  
 )  
Mary Jane Olsen )  
Case No. 2:12-cv-00470 )  
 )  
Virginia White )  
Case No. 2:12-cv-00958 )  
 )  
Sandra Wolfe )  
Case No. 2:12-cv-00335 )  
 )  
Marie Smith (f/k/a Banks) )  
Case No. 2:12-cv-01318 )  
 )  
Sherry Fox )  
Case No. 2:12-cv-00878 )  
 )  
Lois Durham )  
Case No. 2:12-cv-00760 )  
 )  
Elizabeth Blynn Wilson )  
Case No. 2:12-cv-01286 )

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<p style="text-align: right;">Page 139</p> <p>1 Daphne Barker ) Case No. 2:12-cv-00899 ) 2 ) 3 Wendy Hagans ) Case No. 2:12-cv-00783 ) 4 ) 5 Maria Eugenia Quijano ) Case No. 2:12-cv-00799 ) 6 ) 7 Sharon Boggs ) Case No. 2:12-cv-00368 ) 8 ) 9 Robin Bridges ) Case No. 2:12-cv-00651 ) 10 ) 11 Carey Cole ) Case No. 2:12-cv-00483 ) 12 ) 13 Cathy Warlick ) Case No. 2:12-cv-00276 ) 14 ) 15 Donna Amsden ) Case No. 2:12-cv-00960 ) 16 ) 17 Heather Long ) Case No. 2:12-cv-01275 ) 18 ) 19 Penny Rhynehart ) Case No. 2:12-cv-01119 ) 20 ) 21 Nancy Jo Williams ) Case No. 2:12-cv-00511 ) 22 ) 23 Maria Stone ) Case No. 2:12-cv-00652 ) 24 ) Teri Key Shively ) Case No. 2:12-cv-00379 ) Charlene Logan Taylor ) Case No. 2:12-cv-00376 ) Tina Morrow ) Case No. 2:12-cv-00378 ) Carol Jean Dimock ) Case No. 2:12-cv-00401 )</p>	<p style="text-align: right;">Page 141</p> <p>1 APPEARANCES: 2 WAGSTAFF &amp; CARTMELL, LLP BY: ANDREW N. FAES, ESQUIRE 3 afaes@wcllp.com 4 4740 Grand Avenue, Suite 300 Kansas City, Missouri 64112 (816) 701-1100 5 Counsel for Plaintiffs 6 7 EDWARDS &amp; DE LA CERDA, P.L.L.C. BY: PETER DE LA CERDA, ESQUIRE 8 peter@edwardsdelacerda.com (Via Speakerphone) 3031 Allen Street, Suite 100 9 Dallas, Texas 75204 (214) 550-5239 10 Counsel for Amsden Plaintiff 11 12 HERMAN, HERMAN &amp; KATZ, LLC BY: MIKALIA M. KOTT, ESQUIRE mkott@hklawfirm.com 13 (Via Speakerphone) 820 O'Keefe Avenue 14 New Orleans, Louisiana 70113 (504) 581-4892 15 Counsel for Taylor and Shively Plaintiffs 16 17 THE POTTS LAW FIRM, LLP BY: STEPHEN R. RICKS, ESQUIRE 18 sricks@potts-law.com (Via Speakerphone) 19 100 Waugh Drive, Suite 350 Houston, Texas 77007 20 (713) 963-8881 Counsel for Carpenter Plaintiff 21 22 23 24</p>
<p style="text-align: right;">Page 140</p> <p>1 2 - - - 3 Thursday, March 24, 2016 4 5 - - - 6 Oral Deposition of CHRISTINA 7 PRAMUDJI, M.D., taken pursuant to notice, was 8 held at the Westin Houston, Memorial City, 9 945 Gessner Road, Houston, Texas, beginning 10 at 8:13 a.m., on the above date, before 11 Micheal A. Johnson, Registered Diplomat 12 Reporter, Certified Realtime Reporter, and 13 Notary Public for the State of Texas. 14 15 - - - 16 17 18 19 20 21 GOLKOW TECHNOLOGIES, INC. 22 877.370.3377 ph/917.591.5672 fax deps@golkow.com 23 24</p>	<p style="text-align: right;">Page 142</p> <p>1 APPEARANCES: 2 BUTLER SNOW LLP BY: WILLIAM M. GAGE, ESQUIRE 3 william.gage@butlersnow.com 4 1020 Highland Colony Parkway Suite 1400 5 Ridgeland, Mississippi 39157 (601) 948-5711 6 Counsel for Defendants 7 8 - - - 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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<p style="text-align: right;">Page 143</p> <p>1 INDEX CHRISTINA PRAMUDJI, M.D. 2 March 24, 2016 3 4 APPEARANCES 142 5 6 EXAMINATION OF CHRISTINA PRAMUDJI, M.D.: 7 BY MR. FAES 145 8 BY MR. GAGE 255 9 BY MR. FAES 264 10 11 CERTIFICATE 267 12 ERRATA 276 13 ACKNOWLEDGMENT OF DEPONENT 270 14 LAWYER'S NOTES 271 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 145</p> <p>1 PROCEEDINGS 2 CHRISTINA PRAMUDJI, M.D. 3 having been first duly sworn, 4 testified as follows: 5 EXAMINATION 6 BY MR. FAES: 7 Q. Dr. Pramudji, we're back on the 8 record after an overnight break. Are you 9 ready to proceed? 10 A. Yes. 11 Q. Doctor, before we broke last 12 night, we were discussing some things about 13 the Prosima and Prolift IFU, but before we 14 get back into that, I just want to ask you a 15 different question before I forget. 16 Do you do hernia repairs in 17 your practice? 18 A. Abdominal wall hernia repairs? 19 Q. Yes. 20 A. No. 21 Q. Have you ever done hernia 22 repairs in your medical career? 23 A. Yes, I have done them in my 24 training, and maybe a small umbilical hernia</p>
<p style="text-align: right;">Page 144</p> <p>1 DEPOSITION EXHIBITS CHRISTINA PRAMUDJI, M.D. 2 March 24, 2016 3 4 NUMBER DESCRIPTION MARKED 5 Exhibit 11 Gynecare Prosima IFU 155 6 Exhibit 12 Gynecare Gynemesh PS IFU 162 7 Exhibit 13 Christina Pramudji 181 Reliance List, in 8 Addition to Materials 9 Referenced in Report, MDL Wave I 10 Exhibit 14 03/29/2009 through 243 03/30/2009 E-mail String 11 12 Exhibit 15 02/27/2008 Letter, 246 Ethicon Women's Health &amp; Urology to Price St. 13 Hilaire 14 Exhibit 16 01/13/2009 E-mail, 247 Chaves to Lynn, et al, with Attachment 15 16 Exhibit 17 Zoomerang Questions 247 Comments - Dave Robinson 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 146</p> <p>1 repair on a case years ago. 2 Q. When was that? 3 A. I don't know. Eight or 4 ten years ago. We were going in for other 5 reasons and just put in a couple of sutures 6 at that time. 7 Q. Do you sometimes find, when 8 you're repairing a prolapse, small umbilical 9 hernias that need repair? 10 A. Occasionally find an umbilical 11 hernia or an inguinal hernia. My norm is to 12 call general surgery and have them come in 13 and repair it. 14 Q. Okay. Thank you. You 15 anticipated my next question, which is, it's 16 your typical practice not to try to repair 17 those small umbilical hernias yourself but to 18 refer it out to a physician who has more 19 experience in that area? 20 A. That's correct. 21 Q. When you -- do you recall 22 the -- you might have already answered this. 23 Do you recall approximately when these 24 hernias were that you repaired, the couple</p>

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<p style="text-align: right;">Page 147</p> <p>1 that you did years ago?</p> <p>2 A. I don't recall.</p> <p>3 Q. Do you recall what -- if you</p> <p>4 used polypropylene mesh to repair those</p> <p>5 hernias?</p> <p>6 A. On those incidental cases, that</p> <p>7 would have just been sutures. But in</p> <p>8 residency when I repaired multiple during my</p> <p>9 general surgery, and that would have been</p> <p>10 going back to 1996, 1997, then we would use</p> <p>11 mesh.</p> <p>12 Q. Do you recall what meshes you</p> <p>13 used in 1996 --</p> <p>14 A. No.</p> <p>15 Q. -- at that time? But it's fair</p> <p>16 to say it wouldn't have been the Gynemesh PS</p> <p>17 in 1996 because it wasn't being made at that</p> <p>18 time, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So getting back to the IFU, let</p> <p>21 me ask you this, Doctor. If Ethicon said</p> <p>22 something in the IFU which Ethicon knew not</p> <p>23 to be true, would you agree that that would</p> <p>24 be wrongful?</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. So what -- in what situations</p> <p>2 do you believe it would not be wrongful for</p> <p>3 Ethicon to make claims about that it had no</p> <p>4 data to support?</p> <p>5 A. I don't know. That's a very</p> <p>6 difficult question to answer. It's a</p> <p>7 hypothetical within a hypothetical, so I</p> <p>8 don't know if I could come up with any</p> <p>9 specific things.</p> <p>10 Q. So as you sit here today, your</p> <p>11 answer to the question if Ethicon made claims</p> <p>12 about the mesh in the Prolift or Prosima</p> <p>13 device that Ethicon had no data to support,</p> <p>14 your answer to whether or not that would be</p> <p>15 wrongful would be "it depends," but you can't</p> <p>16 think of any situations, as you sit here</p> <p>17 today, in which it would be okay?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 A. That's correct.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Are you aware of anything in</p> <p>22 the Prolift or Prosima IFU as to which anyone</p> <p>23 at Ethicon has admitted that there was not</p> <p>24 data to support the claim about the mesh?</p>
<p style="text-align: right;">Page 148</p> <p>1 A. Yes. I mean, depending on --</p> <p>2 yeah, I think if there's something that they</p> <p>3 knew not to be wrongful and it had -- it was</p> <p>4 a substantial fact, I would have to say that</p> <p>5 would be wrong.</p> <p>6 Q. If Ethicon made claims about</p> <p>7 the mesh in the Prolift or Prosima device</p> <p>8 that Ethicon had no data to support, would</p> <p>9 that be wrongful?</p> <p>10 A. It depends on what their --</p> <p>11 what issues they're referring to.</p> <p>12 Q. So your answer to that question</p> <p>13 is "it depends"?</p> <p>14 A. That's correct, it depends.</p> <p>15 Q. If Ethicon made claims about</p> <p>16 the mesh in the Prolift or Prosima device</p> <p>17 which it had no data to support and those</p> <p>18 claims were related to the clinical effects</p> <p>19 of the mesh, would that be wrongful?</p> <p>20 A. It still depends on what it is.</p> <p>21 It's -- you start out with a certain body of</p> <p>22 data and then the -- you gather more data as</p> <p>23 you go along. So it depends on what the</p> <p>24 issue is.</p>	<p style="text-align: right;">Page 150</p> <p>1 A. Not that I'm aware of.</p> <p>2 Q. If that occurred and the</p> <p>3 statement in the IFU affected the clinical</p> <p>4 performance of the mesh, would you agree that</p> <p>5 that would be a failure to provide adequate</p> <p>6 and appropriate warnings about the Prolift</p> <p>7 and Prosima devices?</p> <p>8 A. Can you repeat the question?</p> <p>9 MR. FAES: May I have the court</p> <p>10 reporter read it back because I don't</p> <p>11 know if I can.</p> <p>12 (Question Read Back.)</p> <p>13 MR. GAGE: Object to form.</p> <p>14 A. What is "that"? What was</p> <p>15 "that" referring to at the beginning? What</p> <p>16 was the question before that?</p> <p>17 BY MR. FAES:</p> <p>18 Q. The previous question was about</p> <p>19 making a claim which there was no data to</p> <p>20 support, a claim about the mesh which</p> <p>21 affected its clinical performance.</p> <p>22 A. Okay. Now, can you read the</p> <p>23 last question one more time, please.</p> <p>24 (Question Read Back.)</p>

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<p style="text-align: right;">Page 151</p> <p>1 MR. GAGE: Object to form.</p> <p>2 A. No, not necessarily. Again, it</p> <p>3 depends.</p> <p>4 BY MR. FAES:</p> <p>5 Q. In what situations would that</p> <p>6 not be a failure to provide an adequate and</p> <p>7 appropriate warning?</p> <p>8 A. I can't think of any specific</p> <p>9 examples that I can give you.</p> <p>10 Q. Are you aware of any Ethicon</p> <p>11 deposition testimony admitting anything about</p> <p>12 the mesh which is contrary to what is</p> <p>13 represented in the IFU regarding the</p> <p>14 Gynemesh PS or the devices which contain the</p> <p>15 Gynemesh PS?</p> <p>16 A. Not that I can recall sitting</p> <p>17 here right now.</p> <p>18 Q. If that occurred, would you</p> <p>19 agree that it would be a failure to provide</p> <p>20 adequate and appropriate warnings about the</p> <p>21 Prosima, Prolift and Gynemesh PS?</p> <p>22 MR. GAGE: Objection.</p> <p>23 A. No, not necessarily.</p> <p>24 BY MR. FAES:</p>	<p style="text-align: right;">Page 153</p> <p>1 the Prosima?</p> <p>2 A. It depends on the patient. So</p> <p>3 there's some patients that really need to</p> <p>4 have a mesh augmentation and some patients</p> <p>5 that can do okay without a mesh augmentation.</p> <p>6 Q. Is your answer the same with</p> <p>7 regard to the Prolift device?</p> <p>8 A. Yes.</p> <p>9 Q. Is your answer the same with</p> <p>10 regard to the Gynemesh PS device?</p> <p>11 A. Yes. Some patients really</p> <p>12 benefit from mesh augmentation, many</p> <p>13 patients.</p> <p>14 MR. FAES: I'm going to move to</p> <p>15 strike after the answer "yes."</p> <p>16 BY MR. FAES:</p> <p>17 Q. So is it your opinion that even</p> <p>18 if a patient can benefit from mesh</p> <p>19 augmentation, that using -- that -- strike</p> <p>20 that.</p> <p>21 So is it your opinion that even</p> <p>22 if a patient can benefit from mesh</p> <p>23 augmentation, it's your opinion that in those</p> <p>24 patients mesh should not be used judiciously?</p>
<p style="text-align: right;">Page 152</p> <p>1 Q. So it's your opinion that it's</p> <p>2 not a failure to warn, even if Ethicon</p> <p>3 provided information about the mesh it knew</p> <p>4 to be unsupported or made an affirmative</p> <p>5 representation about the mesh it knew not to</p> <p>6 be true, even if it affected its clinical</p> <p>7 performance? That's okay with you?</p> <p>8 MR. GAGE: Object to form.</p> <p>9 A. That's a very long question.</p> <p>10 That's correct, not necessarily. There are</p> <p>11 certain -- I can imagine certain situations</p> <p>12 where there would be -- where that would not</p> <p>13 be a problem at all.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Okay. Let me ask you the --</p> <p>16 strike that.</p> <p>17 Let me ask if you -- you if</p> <p>18 the -- strike that again.</p> <p>19 Let me ask you if the following</p> <p>20 statement is true with regard to the Prosima.</p> <p>21 Considering that native tissue repair is an</p> <p>22 option for many women, it makes sense to use</p> <p>23 vaginal mesh judiciously in vaginal mesh</p> <p>24 repairs. Is that a true statement regarding</p>	<p style="text-align: right;">Page 154</p> <p>1 MR. GAGE: Object to form.</p> <p>2 A. No. My opinion is that all</p> <p>3 surgeries should be done judiciously, whether</p> <p>4 with mesh or with biological graft or without</p> <p>5 mesh. Every surgery is done judiciously.</p> <p>6 BY MR. FAES:</p> <p>7 Q. So it's your opinion that while</p> <p>8 every surgery should be done judiciously, it</p> <p>9 doesn't make sense to use vaginal mesh</p> <p>10 judiciously for some mesh repairs if the</p> <p>11 patient can benefit from the mesh?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. No, I think every surgery is</p> <p>14 done judiciously, whether using mesh or not.</p> <p>15 BY MR. FAES:</p> <p>16 Q. So I'm just trying to</p> <p>17 understand your opinions, Doctor. You</p> <p>18 think -- you believe every surgery should be</p> <p>19 done judiciously. Do you believe vaginal</p> <p>20 mesh should be used judiciously in every</p> <p>21 case?</p> <p>22 A. Absolutely.</p> <p>23 Q. Okay. Let me ask you something</p> <p>24 very specific about the Prosima IFU. What</p>

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<p>1 specific information would you say actually  2 needed to be in there to warn doctors about  3 complications? What do you think it needs to  4 say?  5 A. Well, the only risk unique to a  6 mesh implant is a mesh exposure or erosion.  7 And other than that, I think they could say  8 it has the same risks as any other pelvic  9 surgery.  10 Q. So your opinion is, if the  11 adverse reaction section of the Prosima IFU  12 said the Prosima has the same risks as any  13 pelvic surgery and also the risk of erosion  14 or exposure of the mesh, that would be --  15 that would be a sufficient IFU with regard to  16 the adverse reaction section?  17 A. Yes.  18 Q. But you know -- and feel free  19 to refer to the Prosima IFU in front of you  20 that we marked yesterday. I can't remember.  21 We'll re-mark it as Exhibit 11 since the  22 court reporter ran off with the exhibits  23 yesterday.  24 (Deposition Exhibit 11 marked.)</p>	<p>1 question again, and I'm going to ask you  2 to -- if you need to offer an explanation  3 after the answer, do so, but if you can,  4 please first answer the question yes or no.  5 MR. GAGE: Hang on a second.  6 As I understand it, the court rules  7 are she can answer yes, followed by an  8 explanation; no, followed by an  9 explanation; or she can answer, I  10 can't answer it yes or no.  11 MR. FAES: I'll agree with  12 that.  13 MR. GAGE: Those are the rules  14 of court.  15 BY MR. FAES:  16 Q. So is it your opinion as an  17 expert for Ethicon that everything in this  18 adverse reaction section for the Prosima IFU,  19 other than erosion exposure and the same  20 risks as any pelvic surgery, are unnecessary?  21 A. I wouldn't say yes or no to  22 that. I would say that's fine if they put  23 that in there, but it doesn't really add  24 anything to the knowledge of a pelvic</p>
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<p>1 BY MR. FAES:  2 Q. So is it your opinion that  3 everything else that's in this adverse  4 reaction section is unnecessary?  5 A. Yes.  6 Q. So it's your opinion, as an  7 expert for Ethicon, that Ethicon puts  8 unnecessary information in the IFU?  9 A. That's a funny way to put it.  10 I would say it's redundant for a pelvic  11 surgeon that would be using this. They would  12 know about all these risks. And someone  13 that's using the Prosima, frankly, would know  14 about the risk of mesh exposure. So I do --  15 I think -- I wouldn't say they're  16 unnecessary. I would just say that they're  17 redundant and just sort of extra information.  18 I don't have a problem with it. They can  19 put --  20 Q. I'm going to re-ask the  21 question. I think you answered the question  22 in there somewhere, but you added a lot of  23 other things about whether you thought it was  24 redundant or not. So I'm going to ask the</p>	<p>1 surgeon.  2 Q. But you can't answer whether or  3 not the -- any of the extra information is  4 unnecessary or not?  5 A. That's correct.  6 Q. Would you agree that providing  7 this information that -- other than -- strike  8 that.  9 Would you provide [sic] that  10 providing information in the adverse reaction  11 section, other than just erosion exposure and  12 the same risks as pelvic surgery, can be  13 helpful to some surgeons in reminding them  14 about the adverse reactions of the device?  15 MR. GAGE: Object to form.  16 A. Sure, it can be a reminder.  17 Sort of like McDonald's coffee, be careful,  18 it's hot, don't spill it.  19 MR. FAES: I'm going to move --  20 object and move to strike after the  21 word "reminder."  22 BY MR. FAES:  23 Q. Doctor, I'm going to ask you  24 about some -- a list of adverse reactions,</p>

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<p style="text-align: right;">Page 159</p> <p>1 and I'm going to ask you if they are 2 potential risks of the Gynemesh PS, Prolift 3 and Prosima device. Okay? 4 Is bleeding a risk of those 5 devices? 6 A. Yes, it is, as with all pelvic 7 surgery. 8 Q. Is hemorrhage or hematoma a 9 risk of those devices? 10 A. Yes, as it is with all pelvic 11 surgery. 12 Q. Is urinary incontinence a risk 13 of those devices? 14 A. Yes, as with all pelvic 15 surgery. 16 Q. Is urge incontinence a risk of 17 those devices? 18 A. Yes, same with all pelvic 19 surgery. 20 Q. Is urinary frequency, urinary 21 retention or obstruction a risk of those 22 devices? 23 A. Yes, same with other pelvic 24 surgeries.</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Pelvic pain or pain with 2 intercourse which in some patients may not 3 resolve? 4 A. Yes, same as other pelvic 5 surgeries. 6 Q. Excessive contraction or 7 shrinkage of the tissue surrounding the mesh? 8 A. Yes. And that -- you can have 9 excessive contraction even without mesh. 10 Q. Punctures or lacerations of 11 vessels, nerve structures or organs, 12 including the bladder, urethra or bowel which 13 may occur and may require surgical repair? 14 A. Yes, same as other pelvic 15 surgeries. 16 Q. Neuromuscular problems, 17 including acute and/or chronic pain in the 18 groin, thigh, leg, pelvic and/or abdominal 19 area which may occur? 20 A. Yes, same as other pelvic 21 surgeries. 22 Q. And all of these adverse 23 reactions may require surgical treatment? 24 A. Yes, the same as other pelvic</p>
<p style="text-align: right;">Page 160</p> <p>1 Q. Is voiding obstruction a risk 2 of those devices? 3 A. Yes, same with other pelvic 4 surgeries. 5 Q. Acute and/or chronic pain? 6 A. Yes, same with other pelvic 7 surgeries. 8 Q. Wound dehiscence? 9 A. Yes, same as other pelvic 10 surgeries. 11 Q. Nerve damage? 12 A. Yes, same as other pelvic 13 surgeries. 14 Q. Recurrent prolapse? 15 A. Yes, same as other pelvic 16 surgeries. 17 Q. Foreign body response? 18 A. Yes, same with other pelvic 19 surgeries. 20 Q. The potential to impair normal 21 voiding function for a variable length of 22 time? 23 A. Yes, same as other pelvic 24 surgeries.</p>	<p style="text-align: right;">Page 162</p> <p>1 surgeries. 2 Q. Is it your opinion that all of 3 those risks that I just read to you are 4 unnecessary to be included in the Prolift, 5 Prosima or Gynemesh IFU? 6 A. That's correct. They are part 7 of the body of knowledge of pelvic surgeons, 8 so I think they don't necessarily have to be 9 in there. 10 Q. Do you know whether or not 11 those risks are in the Gynemesh PS IFU today? 12 A. I would have to review it. I 13 don't have a problem if they're in there. 14 Q. Do you know whether or not all 15 of the adverse events I just read to you were 16 added in 2015? 17 A. I would have to look at it. I 18 don't know. 19 (Deposition Exhibit 12 marked.) 20 BY MR. FAES: 21 Q. I'm going to hand you what's 22 been marked as Exhibit No. 12 to your 23 deposition. 24 MR. FAES: Do you want one,</p>

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<p style="text-align: right;">Page 163</p> <p>1 William?</p> <p>2 MR. GAGE: Yeah. Thank you.</p> <p>3 BY MR. FAES:</p> <p>4 Q. So I'll represent to you that</p> <p>5 those are all risks that were added to the</p> <p>6 Gynemesh PS IFU beginning with this revision</p> <p>7 that Ethicon released in 2015, and the front</p> <p>8 page of this is dated February 3rd, 2015.</p> <p>9 Do you know whether or not</p> <p>10 these are all risks of the Prosima, Prolift</p> <p>11 and Gynemesh PS device that Ethicon knew</p> <p>12 about when those devices were first launched</p> <p>13 onto the market?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I'm not sure. I don't know.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Do you know whether or not</p> <p>18 Ethicon could've chosen to include all of</p> <p>19 these risks in their IFU --</p> <p>20 A. I would --</p> <p>21 Q. -- from the -- sorry, I wasn't</p> <p>22 done with the question. I'll start over.</p> <p>23 Do you know whether or not</p> <p>24 Ethicon could have chosen to include all of</p>	<p style="text-align: right;">Page 165</p> <p>1 Ethicon would knowingly put things in the IFU</p> <p>2 that it believed to be unnecessary?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. I don't know what they knew or</p> <p>5 didn't know.</p> <p>6 BY MR. FAES:</p> <p>7 Q. Now, you -- strike that.</p> <p>8 You testified that it was your</p> <p>9 typical practice to read the IFU before</p> <p>10 implanting the device for the first time,</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. And you typically wouldn't</p> <p>14 re-review the IFU unless you were aware that</p> <p>15 there was a change to that IFU, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Would you have any way of</p> <p>18 knowing, unless you closely examined the IFU,</p> <p>19 that there had been an important IFU update?</p> <p>20 A. Not that I'm aware of.</p> <p>21 Q. Do you think it would be --</p> <p>22 strike that.</p> <p>23 You're a past user of</p> <p>24 Gynemesh PS, correct?</p>
<p style="text-align: right;">Page 164</p> <p>1 these risks in their IFUs for the Gynemesh</p> <p>2 PS, Prolift and Prosima device beginning from</p> <p>3 the first day that they were launched in the</p> <p>4 United States?</p> <p>5 A. I would have to say, sure,</p> <p>6 theoretically, you could come up with a long</p> <p>7 laundry list of things that you could put in</p> <p>8 the IFU. So, sure, theoretically they could</p> <p>9 have put them in from the beginning.</p> <p>10 Q. Do you know whether or not</p> <p>11 Ethicon felt it was necessary to add these</p> <p>12 adverse events to their IFU in 2015?</p> <p>13 A. No, I don't know what they</p> <p>14 thought.</p> <p>15 Q. Do you believe, as an expert</p> <p>16 for Ethicon, that Ethicon would knowingly put</p> <p>17 things in the IFU that it believed to be</p> <p>18 unnecessary?</p> <p>19 MR. GAGE: Object to form.</p> <p>20 A. Can you read back the question</p> <p>21 or can you repeat it?</p> <p>22 BY MR. FAES:</p> <p>23 Q. I'll repeat it. Do you</p> <p>24 believe, as an expert for Ethicon, that</p>	<p style="text-align: right;">Page 166</p> <p>1 A. Correct.</p> <p>2 Q. Do Ethicon sales reps know that</p> <p>3 you've used Gynemesh PS and products that</p> <p>4 contain Gynemesh PS in the past?</p> <p>5 A. Yes.</p> <p>6 Q. Has anyone from Ethicon ever</p> <p>7 informed you that the IFU for the Gynemesh PS</p> <p>8 was updated in 2015?</p> <p>9 A. No, and I wouldn't expect them</p> <p>10 to. If you have a surgeon that's familiar</p> <p>11 with the product, they're having good</p> <p>12 results, it's not going to change anything.</p> <p>13 Q. Isn't it possible that there</p> <p>14 are -- strike that.</p> <p>15 Do you think it would be a</p> <p>16 reasonable thing to do, for Ethicon to inform</p> <p>17 doctors that there is a new IFU for its</p> <p>18 products out there that may contain important</p> <p>19 adverse reactions that were not contained in</p> <p>20 the previous IFU?</p> <p>21 A. Sure, it's reasonable. I</p> <p>22 wouldn't say that's unreasonable.</p> <p>23 Q. Do you think it would be</p> <p>24 helpful for Ethicon to inform doctors that</p>

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<p style="text-align: right;">Page 167</p> <p>1 there's a new IFU out there for its products</p> <p>2 that may contain important adverse reactions</p> <p>3 that were not contained in the previous IFU?</p> <p>4 A. Not particularly, because we</p> <p>5 already know about all this.</p> <p>6 Q. So you believe that every</p> <p>7 surgeon in America knows about all of the new</p> <p>8 adverse reactions that were added to the</p> <p>9 Gynemesh PS IFU in 2015?</p> <p>10 A. Did you mean to say "every</p> <p>11 surgeon" or "every pelvic surgeon"?</p> <p>12 Q. I'll restate it as every pelvic</p> <p>13 surgeon. So you believe that every pelvic</p> <p>14 surgeon in America knows about all of the new</p> <p>15 adverse reactions that were added to the</p> <p>16 Gynemesh PS IFU in 2015?</p> <p>17 A. Well, I don't know what they</p> <p>18 would know about the IFU. But I would say</p> <p>19 that a pelvic surgeon that is familiar with</p> <p>20 pelvic surgery, familiar with mesh, would</p> <p>21 definitely be aware of these adverse</p> <p>22 reactions.</p> <p>23 MR. FAES: I'm going to object</p> <p>24 and move to strike after the word</p>	<p style="text-align: right;">Page 169</p> <p>1 use for a particular medical device that the</p> <p>2 FDA deemed important, do you think that that</p> <p>3 would be something that would be reasonable</p> <p>4 for a medical device company to communicate</p> <p>5 to surgeons who they knew used the device?</p> <p>6 A. Again, it depends what it is,</p> <p>7 depends if it's going to affect how you</p> <p>8 implant it, you use it and what the nature of</p> <p>9 the update is.</p> <p>10 Q. I think yesterday you testified</p> <p>11 that you believe the Gynemesh PS was still</p> <p>12 indicated for transvaginal placement.</p> <p>13 A. I believe it is.</p> <p>14 Q. Do you want to take a moment to</p> <p>15 read the indications for use in this updated</p> <p>16 2015 IFU and tell me if you -- after</p> <p>17 reviewing that, if you still believe that's</p> <p>18 the case?</p> <p>19 (Witness Reviews Document.)</p> <p>20 A. It says here that it's</p> <p>21 "indicated as a bridging material for apical</p> <p>22 vaginal and uterine prolapse where surgical</p> <p>23 treatment (laparotomy or laparoscopic</p> <p>24 approach) is warranted."</p>
<p style="text-align: right;">Page 168</p> <p>1 "IFU."</p> <p>2 BY MR. FAES:</p> <p>3 Q. Have you done any kind of</p> <p>4 research or survey to determine -- strike</p> <p>5 that.</p> <p>6 Have you done any kind of</p> <p>7 research or survey or study to determine what</p> <p>8 the typical pelvic surgeon in the United</p> <p>9 States knows about the adverse reactions of</p> <p>10 the Gynemesh PS, Prolift and Prosima device?</p> <p>11 A. No, I haven't done any research</p> <p>12 like that.</p> <p>13 Q. If there were an important</p> <p>14 update to the indications for use for a</p> <p>15 particular medical device, do you think that</p> <p>16 would be something that would be reasonable</p> <p>17 for a medical device company to communicate</p> <p>18 to surgeons who they knew used the device?</p> <p>19 A. Depends on what you mean by</p> <p>20 "important." Who considers it important?</p> <p>21 The surgeons or the attorneys?</p> <p>22 Q. Well, you know that the -- I'm</p> <p>23 not -- okay. Let me ask it this way. If</p> <p>24 there were a update to the indications for</p>	<p style="text-align: right;">Page 170</p> <p>1 So apparently they're using it</p> <p>2 more for intraabdominal for that indication</p> <p>3 at this point. So I was not aware of that</p> <p>4 change.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Were you aware that this change</p> <p>7 actually occurred not with the 2015 IFU but</p> <p>8 with the 2013 IFU?</p> <p>9 A. No, I didn't know about that.</p> <p>10 Q. So you didn't know, as an</p> <p>11 expert offering opinions on the Gynemesh PS</p> <p>12 mesh, that the indications for use for the</p> <p>13 device changed nearly three years ago?</p> <p>14 A. No.</p> <p>15 MR. GAGE: Objection.</p> <p>16 A. As I mentioned, I haven't used</p> <p>17 Gynemesh for several years, so I was not</p> <p>18 aware of that.</p> <p>19 BY MR. FAES:</p> <p>20 Q. Since the indications for use</p> <p>21 for the Gynemesh PS mesh have changed as of</p> <p>22 2013, would it be reasonable to assume that</p> <p>23 indications for use for the Prosima and</p> <p>24 Prolift device would have changed as well if</p>

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<p style="text-align: right;">Page 171</p> <p>1 those products were still on the market?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't think so because those</p> <p>4 are specifically transvaginal kits. So I</p> <p>5 don't know what other indication that they</p> <p>6 could put besides transvaginal placement.</p> <p>7 BY MR. FAES:</p> <p>8 Q. But you know that the FDA has</p> <p>9 told Ethicon that they can no longer sell the</p> <p>10 Prosima or Prolift device unless they</p> <p>11 complete a 522 order, correct?</p> <p>12 A. I believe that's correct.</p> <p>13 MR. GAGE: Object to form.</p> <p>14 BY MR. FAES:</p> <p>15 Q. And you know that the FDA</p> <p>16 agreed that the Prolift and Prosima 522 plans</p> <p>17 could be placed on hold if Ethicon -- if</p> <p>18 Ethicon agreed not to sell those devices</p> <p>19 anymore, correct?</p> <p>20 A. I don't know about those</p> <p>21 details.</p> <p>22 Q. You don't know about those</p> <p>23 details?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 173</p> <p>1 BY MR. FAES:</p> <p>2 Q. Do you know that -- whether or</p> <p>3 not Ethicon negotiated with the FDA to keep</p> <p>4 Gynemesh PS on the market, and a condition of</p> <p>5 their being allowed to keep it on the market</p> <p>6 was to remove the transvaginal indication for</p> <p>7 the Gynemesh PS and have it be indicated for</p> <p>8 abdominal placement only?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. I don't know about that.</p> <p>11 BY MR. FAES:</p> <p>12 Q. Do you think that would be an</p> <p>13 important fact to consider in forming your</p> <p>14 opinions in this case?</p> <p>15 A. No, I don't think that would</p> <p>16 affect my opinion.</p> <p>17 Q. Do you think a surgeon who has</p> <p>18 been using the Gynemesh PS transvaginally</p> <p>19 prior to the IFU update in 2013 would want to</p> <p>20 know about the indication-for-use change if</p> <p>21 he were going to continue using it after the</p> <p>22 indication-for-use change in 2013?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. I think if a surgeon is using</p>
<p style="text-align: right;">Page 172</p> <p>1 Q. Are you aware that if Ethicon</p> <p>2 decides to start selling those devices again,</p> <p>3 they need to notify the FDA before doing so?</p> <p>4 A. I don't know about that detail</p> <p>5 either.</p> <p>6 Q. Assuming that that's true, do</p> <p>7 you think it's reasonable, since it's been</p> <p>8 three years -- over three years since the</p> <p>9 Prosima and Prolift devices were sold and the</p> <p>10 FDA has changed -- had -- strike that.</p> <p>11 Assuming that's true, do you</p> <p>12 think it's reasonable to assume that since</p> <p>13 it's been three years since the Prosima and</p> <p>14 Prolift device has been sold and the</p> <p>15 indications for use for the mesh that is used</p> <p>16 in those devices has changed in that time,</p> <p>17 that the FDA would look closely at the IFUs</p> <p>18 for those devices before allowing that to be</p> <p>19 put -- placed back on the market?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 A. I would imagine that they</p> <p>22 would, but I don't know what the FDA process</p> <p>23 is in detail.</p> <p>24</p>	<p style="text-align: right;">Page 174</p> <p>1 it and is comfortable with it, having good</p> <p>2 results with it, even transvaginally, it's</p> <p>3 not important for them to know.</p> <p>4 BY MR. FAES:</p> <p>5 Q. So it's your testimony that</p> <p>6 you, as a physician, wouldn't want to know if</p> <p>7 you were using a medical device off label</p> <p>8 before you used it off label?</p> <p>9 A. If you're using something with</p> <p>10 good results, literature supports safety and</p> <p>11 efficacy, I think the change of -- the</p> <p>12 off-label change of indication is simply,</p> <p>13 really, semantics in that situation and,</p> <p>14 yeah, it -- I guess you could say it would be</p> <p>15 helpful to know. But I think you would still</p> <p>16 be able to support your use of the device off</p> <p>17 label based on your own results and based on</p> <p>18 the literature that's out there.</p> <p>19 MR. FAES: I'm going to object</p> <p>20 and move to strike just because I'm</p> <p>21 not sure what your answer there was.</p> <p>22 Maybe it's my fault. Maybe I asked a</p> <p>23 bad question, so I'll ask it a little</p> <p>24 bit differently.</p>

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<p style="text-align: right;">Page 175</p> <p>1 BY MR. FAES:</p> <p>2 Q. Would you, as a physician, want</p> <p>3 to know if you were using a medical device</p> <p>4 off label before you used the device?</p> <p>5 A. Not necessarily.</p> <p>6 Q. Do you think other physicians</p> <p>7 would want to know if they were using the</p> <p>8 device off label before they used that</p> <p>9 device?</p> <p>10 A. Not necessarily. I can</p> <p>11 certainly conceive of how this -- how you</p> <p>12 could continue using this off label and feel</p> <p>13 very comfortable and be able to support your</p> <p>14 position for using it off label, even if you</p> <p>15 found out after the fact.</p> <p>16 Q. So is it your opinion -- strike</p> <p>17 that.</p> <p>18 So is it not your typical</p> <p>19 practice to read the instruction -- strike</p> <p>20 that.</p> <p>21 Is it not your typical practice</p> <p>22 to read the indications for use for a medical</p> <p>23 device before deciding how to use that</p> <p>24 medical device?</p>	<p style="text-align: right;">Page 177</p> <p>1 the indications for use for a medical device</p> <p>2 before deciding how to use that medical</p> <p>3 device?</p> <p>4 A. I don't know the answer to that</p> <p>5 question. I don't know how many surgeons</p> <p>6 look at the IFU. I don't know. Because a</p> <p>7 lot of training you learn from other</p> <p>8 surgeons. We rarely learn from the IFU.</p> <p>9 MR. FAES: I'm going to object</p> <p>10 and move -- move to strike after the</p> <p>11 third "I don't know."</p> <p>12 BY MR. FAES:</p> <p>13 Q. Is it your testimony that the</p> <p>14 indications for use in the IFU don't guide</p> <p>15 your decision on how to use that device?</p> <p>16 A. To a certain degree it may</p> <p>17 guide how I use the device, but it's really</p> <p>18 not the primary thing that I rely on, if that</p> <p>19 makes sense. It's sort of supplemental.</p> <p>20 Okay, let's see what it says here, see if</p> <p>21 there's any nuance that I'm not aware of, and</p> <p>22 then proceed as such.</p> <p>23 Q. Would you agree with me that if</p> <p>24 a physician were to place the Gynemesh PS</p>
<p style="text-align: right;">Page 176</p> <p>1 A. Like I said before, when you</p> <p>2 first use something, you review the IFU. But</p> <p>3 after you use it and you're comfortable with</p> <p>4 it, you apply your skills as a surgeon.</p> <p>5 That's what's more important, not -- we don't</p> <p>6 live and die by the IFU. We don't function</p> <p>7 based on the IFU. We function based on our</p> <p>8 skills and training.</p> <p>9 MR. FAES: I'm going to object</p> <p>10 and move to strike. Again, I may have</p> <p>11 asked a bad question so I'll try to</p> <p>12 ask it a little bit better.</p> <p>13 BY MR. FAES:</p> <p>14 Q. Is it your typical practice to</p> <p>15 read the indications for use for a medical</p> <p>16 device before deciding how to use that</p> <p>17 medical device?</p> <p>18 A. No. I don't use it to decide</p> <p>19 how to use the medical device. I use it to</p> <p>20 make sure I understand what the device</p> <p>21 offers, make sure I understand how it's</p> <p>22 intended for use.</p> <p>23 Q. Do you think it's typical</p> <p>24 practice for other pelvic surgeons to read</p>	<p style="text-align: right;">Page 178</p> <p>1 transvaginally today in a surgery in the</p> <p>2 United States, that use would be off label?</p> <p>3 A. Yes, that's correct.</p> <p>4 Q. Would you agree with me that if</p> <p>5 a physician were to place the Gynemesh PS</p> <p>6 transvaginally today in the surgery -- strike</p> <p>7 that.</p> <p>8 Would you agree with me that if</p> <p>9 a physician were to place the Gynemesh PS</p> <p>10 transvaginally today in the United States,</p> <p>11 that would be contrary to the indications for</p> <p>12 use as currently stated in the IFU?</p> <p>13 A. Yes, I would have to agree with</p> <p>14 that based on what the IFU says here.</p> <p>15 Q. I think I'm done with that for</p> <p>16 now. You can set that aside.</p> <p>17 Doctor, I'm going to mark</p> <p>18 another copy of your --</p> <p>19 MR. GAGE: FYI, the Wolfe depo</p> <p>20 has been postponed. I just got the</p> <p>21 e-mail.</p> <p>22 MR. FAES: Exciting news. Do</p> <p>23 you have another copy of her op</p> <p>24 report, William?</p>

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<p style="text-align: right;">Page 179</p> <p>1 (Discussion Off The Record.)</p> <p>2 BY MR. FAES:</p> <p>3 Q. Doctor, I'm just going to ask</p> <p>4 you -- I'm going to want to ask you a few</p> <p>5 questions about your pelvic organ prolapse</p> <p>6 report. If you need to refer to -- back to</p> <p>7 it, the court reporter took off with it. I</p> <p>8 can give you my copy if you really need it.</p> <p>9 MR. GAGE: Well, but you had it</p> <p>10 in your notebook, didn't you?</p> <p>11 THE WITNESS: That big one. I</p> <p>12 think it might be that one on the top.</p> <p>13 BY MR. FAES:</p> <p>14 Q. I think you can probably answer</p> <p>15 these questions without looking at it, but I</p> <p>16 don't want you to be handicapped by not</p> <p>17 having it available.</p> <p>18 MR. FAES: Yeah, we're still on</p> <p>19 the Prolift deposition.</p> <p>20 BY MR. FAES:</p> <p>21 Q. Now, in your report in your</p> <p>22 reliance list, there's medical literature</p> <p>23 that you cite in both your report and on your</p> <p>24 reliance list. Have you read all those</p>	<p style="text-align: right;">Page 181</p> <p>1 your opinions in this case?</p> <p>2 A. It depends on what it is.</p> <p>3 Q. But you would agree that it's</p> <p>4 possible that there could be literature or</p> <p>5 data out there that could change your</p> <p>6 opinions in this case and you can't know</p> <p>7 whether it's significant unless you see it,</p> <p>8 correct?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. No, I would disagree. I think</p> <p>11 that's very unlikely because I feel very</p> <p>12 comfortable with the literature that I have</p> <p>13 here and my own experience. My opinions are</p> <p>14 very firm.</p> <p>15 BY MR. FAES:</p> <p>16 Q. So you believe it's very</p> <p>17 unlikely. But do you believe it's possible?</p> <p>18 A. I think it's next to</p> <p>19 impossible.</p> <p>20 Q. I'm just going to leave that</p> <p>21 alone.</p> <p>22 (Deposition Exhibit 13 marked.)</p> <p>23 BY MR. FAES:</p> <p>24 Q. Just so you have it, Doctor,</p>
<p style="text-align: right;">Page 180</p> <p>1 articles?</p> <p>2 A. I've at least perused them. I</p> <p>3 wouldn't say that I've read them all in</p> <p>4 detail.</p> <p>5 Q. Would you agree that the list</p> <p>6 of medical literature and articles in your</p> <p>7 report and your reliance list is not a</p> <p>8 comprehensive list of all the articles and</p> <p>9 literature that's available on the Prosima,</p> <p>10 Gynemesh PS or Prolift?</p> <p>11 A. Probably not.</p> <p>12 Q. Is it possible there's clinical</p> <p>13 data that you didn't see, which, if you saw,</p> <p>14 could change your opinions in this case?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. It's possible there's</p> <p>17 literature I haven't seen, but I think I've</p> <p>18 got the -- most of the level 1 literature, so</p> <p>19 I doubt there's something that would change</p> <p>20 my opinions.</p> <p>21 BY MR. FAES:</p> <p>22 Q. Would you agree with me that</p> <p>23 unless you see such data, you can't assess</p> <p>24 whether it's significant to you in forming</p>	<p style="text-align: right;">Page 182</p> <p>1 I'm going to -- you're going to need this</p> <p>2 eventually for your TVT deposition later</p> <p>3 anyway, I'm going to re-mark a copy of your</p> <p>4 reliance list for all your expert reports as</p> <p>5 Exhibit 13 for the record.</p> <p>6 A. Okay.</p> <p>7 Q. Now, there's a lot of different</p> <p>8 articles that you cite in your Gynemesh PS,</p> <p>9 Prolift and Prosima report. Did you</p> <p>10 deliberately not cite to articles that were</p> <p>11 not favorable to those products?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. No, I didn't deliberately. I</p> <p>14 tried to pick out the articles which I</p> <p>15 thought had the best data as far as the most</p> <p>16 rigorous data, whether it was favorable or</p> <p>17 not.</p> <p>18 BY MR. FAES:</p> <p>19 Q. I'm going to shift gears a</p> <p>20 little bit, Doctor, and ask you some</p> <p>21 questions about the mesh properties of the</p> <p>22 Gynemesh PS, Prolift and Prosima device.</p> <p>23 Do you know whether or not the</p> <p>24 amount of mesh placed in a woman's pelvis for</p>

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<p style="text-align: right;">Page 183</p> <p>1 the treatment of prolapse has an effect on 2 the intensity and duration of the foreign 3 body reaction and inflammatory response? 4 A. I would say that the more 5 sutures, the more mesh, the more foreign 6 body -- it is a foreign body that's placed, 7 you're going to have more of a foreign body 8 reaction. 9 Q. So you would agree that, in 10 general, the larger the amount and weight of 11 the material, the greater the foreign body 12 reaction and inflammatory response will be? 13 A. Yes. More than likely. 14 However, that doesn't necessarily -- that's a 15 normal reaction that you would expect. It's 16 part of the wound healing. 17 MR. FAES: I'm going to object 18 and move to strike after the word 19 "likely." 20 BY MR. FAES: 21 Q. Doctor, am I correct that you 22 don't hold yourself out to be an expert with 23 regard to the design of medical device -- 24 strike that.</p>	<p style="text-align: right;">Page 185</p> <p>1 very confident and familiar with evaluating 2 the design based on those parameters. 3 BY MR. FAES: 4 Q. Is that the extent of the 5 opinions that I would expect you to offer on 6 the Prosima -- on the design of the Prosima, 7 rather? 8 MR. GAGE: Object to form. 9 A. I may have some other opinions 10 as far as they go to the mesh in general or 11 pelvic floor kits or surgery in general. 12 BY MR. FAES: 13 Q. So you would have opinions on 14 the design of the mesh in general or the 15 design of pelvic floor kits and surgery in 16 general? 17 A. Yes. 18 Q. Would those opinions on the 19 design go beyond how those devices -- you 20 believe those devices worked in your hands? 21 A. Yes, they potentially could. 22 Q. Well, you understand, Doctor, 23 that this is my opportunity here today to 24 learn what your opinions in this case might</p>
<p style="text-align: right;">Page 184</p> <p>1 Doctor, am I correct that you 2 don't hold yourself out to be an expert with 3 regard to the design of medical device kits 4 for the treatment of prolapse? 5 A. I would say that I am somewhat 6 of an expert in that area as far as being a 7 user of the devices and also being involved 8 in some of the labs that are held during the 9 development of devices that I've been 10 involved in. So as far as being asked to 11 evaluate different devices as they're being 12 produced, as far as that goes, I do have some 13 expertise in that area. 14 Q. Well, let me see if I can ask 15 it a different way. Am I correct that I 16 would not expect you to offer design -- 17 strike that. 18 Am I correct that I would not 19 expect you to offer opinions on the design of 20 the Prosima? 21 MR. GAGE: Object to form. 22 A. My opinions would go to how I 23 feel the design is based on use in my hands 24 and based on the patient results. So I feel</p>	<p style="text-align: right;">Page 186</p> <p>1 be. What other opinions might you offer on 2 the design of the Prosima or mesh kits or 3 mesh in general? 4 A. Well, opinions about the design 5 of the mesh in general, the way that the mesh 6 is configured, the size of the pores, the 7 materials that the mesh is made of. Or with 8 the kits, how they're designed, how they -- 9 the development of the kits, the nuances of 10 the trocars and how it worked in patients. 11 Q. Have you ever worked on the 12 design team for a medical device? 13 A. No, only on a consulting basis. 14 Q. Am I correct in that you're not 15 a biomedical engineer? 16 A. I'm not a biomedical engineer. 17 I studied it, but I'm not a biomedical 18 engineer. 19 Q. Do you hold yourself out as an 20 expert in biomedical engineering? 21 A. To the degree that it applies 22 to my practice, yes. 23 Q. Do you know what a design 24 failure modes analysis is?</p>

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<p style="text-align: right;">Page 187</p> <p>1 A. I don't -- I'm not familiar</p> <p>2 with that term.</p> <p>3 Q. Is it fair to say that you have</p> <p>4 never reviewed any design failure mode</p> <p>5 analysis with respect to the Prosima,</p> <p>6 Gynemesh PS or Prolift?</p> <p>7 A. I may have, because just</p> <p>8 breaking down that terminology, I don't -- I</p> <p>9 can't give you a quick definition. But just</p> <p>10 breaking it down, it sounds like it's just</p> <p>11 testing the failure of the design with</p> <p>12 some -- probably some mechanical stretching</p> <p>13 or that sort of thing, but that's my</p> <p>14 conjecture. So I may have read about that.</p> <p>15 Q. Do you know what a process</p> <p>16 failure modes effects analysis is?</p> <p>17 A. I'm not familiar with that</p> <p>18 term.</p> <p>19 Q. Do you recall if you reviewed</p> <p>20 any process failure modes effects analysis</p> <p>21 with the Prosima, Prolift or Gynemesh PS</p> <p>22 devices?</p> <p>23 A. I'm not sure.</p> <p>24 Q. Do you know what an</p>	<p style="text-align: right;">Page 189</p> <p>1 feel very knowledgeable about the type of the</p> <p>2 mesh, the use of the mesh, behavior of the</p> <p>3 mesh.</p> <p>4 BY MR. FAES:</p> <p>5 Q. Do you have any expertise or</p> <p>6 specialized knowledge regarding whether or</p> <p>7 not a 1-millimeter pore size when the mesh is</p> <p>8 used in the body has any advantages or</p> <p>9 disadvantages for the patient?</p> <p>10 A. Yes. I've definitely studied</p> <p>11 the pore sizes and I've seen how the mesh</p> <p>12 behaves in the patients, and I feel like I</p> <p>13 have a very in-depth knowledge about that.</p> <p>14 Q. Let me ask you this. Do you</p> <p>15 believe that it's important for a mesh to</p> <p>16 have a pore size of 1 millimeter or greater</p> <p>17 in all directions in order for the mesh to be</p> <p>18 properly incorporated into the tissues once</p> <p>19 it is placed?</p> <p>20 A. No, I don't think it has to be</p> <p>21 exactly 1 millimeter. Neutrophils and the</p> <p>22 vagina itself are much smaller than that, so</p> <p>23 it doesn't need to be near that size to</p> <p>24 incorporate well and to heal that well.</p>
<p style="text-align: right;">Page 188</p> <p>1 applications failure modes effects analysis</p> <p>2 is?</p> <p>3 A. I'm not sure.</p> <p>4 Q. Do you recall if you've</p> <p>5 reviewed any of those for the Gynemesh PS,</p> <p>6 Prolift or Prosima device?</p> <p>7 A. I'm not sure.</p> <p>8 Q. Do you hold yourself out as</p> <p>9 having expertise or specialized knowledge</p> <p>10 regarding the type of mesh used in the</p> <p>11 Prosima, Prolift -- I guess I'll say</p> <p>12 Gynemesh PS device even though the mesh --</p> <p>13 that's the only thing in the Gynemesh PS</p> <p>14 device is the mesh?</p> <p>15 A. Could you repeat the first part</p> <p>16 of the question?</p> <p>17 Q. Yeah, I'll re-ask it because I</p> <p>18 didn't think it through before I asked it.</p> <p>19 Am I correct in that you don't</p> <p>20 hold yourself out as having expertise or</p> <p>21 specialized knowledge regarding the type of</p> <p>22 mesh used in the Prosima or Prolift device?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. No, that's incorrect because I</p>	<p style="text-align: right;">Page 190</p> <p>1 Because as you know, when we put it in, the</p> <p>2 pores are going to deform somewhat. That's</p> <p>3 to be expected. And even with that, the</p> <p>4 patients clinically heal well and do well</p> <p>5 with good incorporation.</p> <p>6 Q. Do you believe -- you just</p> <p>7 stated that you know that the mesh is at</p> <p>8 times going to deform. Strike that.</p> <p>9 You just stated that you know</p> <p>10 at -- sometimes that the mesh is going to</p> <p>11 deform. Do you believe the mesh can deform</p> <p>12 to the point where the pores are too small</p> <p>13 for good tissue incorporation?</p> <p>14 A. No, I don't think so. I think</p> <p>15 that the cells are microscopic. So they're</p> <p>16 going to be able to get into -- between the</p> <p>17 fibers, no matter what.</p> <p>18 Q. You stated that you don't think</p> <p>19 it's necessary to have a pore size of</p> <p>20 1 millimeter in all directions. What pore</p> <p>21 size do you think is required in order for</p> <p>22 the tissue to be incorporated into the body?</p> <p>23 MR. FAES: You want to take a</p> <p>24 quick break? I need to run to the</p>

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<p style="text-align: right;">Page 191</p> <p>1 restroom anyway. Let's go off the</p> <p>2 record.</p> <p>3 (Recess Taken From 9:09 a.m. To</p> <p>4 9:16 a.m.)</p> <p>5 BY MR. FAES:</p> <p>6 Q. Doctor, we're back on the</p> <p>7 record after a short break. Are you ready to</p> <p>8 proceed?</p> <p>9 A. Yes.</p> <p>10 Q. When we took a break, there was</p> <p>11 a question pending. It looked like you were</p> <p>12 looking at your report, so I'll restate it.</p> <p>13 You stated that you don't think</p> <p>14 it is necessary to have a pore size of</p> <p>15 1 millimeter in all directions. What pore</p> <p>16 size do you think is required in order for</p> <p>17 tissue to be incorporated into the body in</p> <p>18 pelvic organ prolapse surgery with mesh?</p> <p>19 A. So the Amid classification has</p> <p>20 a pore size of greater than 75 microns.</p> <p>21 Q. So if I understand you</p> <p>22 correctly, you're relying on the Amid</p> <p>23 standard for your opinion on how large the</p> <p>24 pore size needs to be?</p>	<p style="text-align: right;">Page 193</p> <p>1 MR. FAES: I'll object and move</p> <p>2 to strike after the answer "thinks."</p> <p>3 BY MR. FAES:</p> <p>4 Q. Do you know what Ethicon --</p> <p>5 strike that.</p> <p>6 Do you know whether or not</p> <p>7 Ethicon scientists and engineers think that</p> <p>8 the Amid standard is outdated?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 A. I don't know what they think</p> <p>11 about that.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Do you know if -- whether or</p> <p>14 not Ethicon scientists and engineers thought</p> <p>15 the Amid standard was outdated as early as</p> <p>16 2005?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 A. No, I don't know about that.</p> <p>19 BY MR. FAES:</p> <p>20 Q. You know that the Amid standard</p> <p>21 was originally developed for hernia repair.</p> <p>22 Do you know whether or not the FDA told</p> <p>23 Ethicon that they don't believe that they can</p> <p>24 leverage their hernia experience for the</p>
<p style="text-align: right;">Page 192</p> <p>1 A. Yes. But even if it were a</p> <p>2 little smaller than that, it would be fine</p> <p>3 because the neutrophiles and the macro</p> <p>4 fascias are much smaller than that. So even</p> <p>5 if it got to a form lower than that, they</p> <p>6 should be able to come in and lay down the</p> <p>7 collagen and the scar tissue and incorporate</p> <p>8 the mesh.</p> <p>9 Q. You know that the Amid standard</p> <p>10 came out in 1998, correct?</p> <p>11 A. Correct.</p> <p>12 Q. And you know that it was</p> <p>13 originally developed for guidance in hernia</p> <p>14 repair, correct?</p> <p>15 A. I believe so.</p> <p>16 Q. Do you know whether or not</p> <p>17 Dr. Amid thinks that his standard applies to</p> <p>18 the type of mesh used in pelvic organ</p> <p>19 prolapse and stress urinary incontinence</p> <p>20 products?</p> <p>21 MR. GAGE: Object to form.</p> <p>22 A. I don't know what he thinks,</p> <p>23 but it's been widely adopted and utilized</p> <p>24 successfully by the pelvic floor literature.</p>	<p style="text-align: right;">Page 194</p> <p>1 pelvic organ prolapse products?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't know about that.</p> <p>4 BY MR. FAES:</p> <p>5 Q. If Ethicon scientists,</p> <p>6 engineers and consultants believed that the</p> <p>7 pore size of the mesh in the Prosima and</p> <p>8 Prolift products needed to be 1 millimeters</p> <p>9 in all directions in order for proper tissue</p> <p>10 integration to occur, you would disagree with</p> <p>11 them, correct?</p> <p>12 A. I think it doesn't have to be</p> <p>13 1 millimeter. It could be smaller. But I</p> <p>14 think 1 millimeter is fine. It works great.</p> <p>15 Q. So is the answer to my question</p> <p>16 yes, if they thought it needed to be a</p> <p>17 minimum of 1 millimeter in all directions in</p> <p>18 order for proper tissue integration to occur,</p> <p>19 you would disagree with them?</p> <p>20 A. Yes, I would disagree.</p> <p>21 Q. Are you forming your opinions</p> <p>22 on the assumption that the only standard for</p> <p>23 pore size that matters is 75 microns?</p> <p>24 A. No.</p>

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<p style="text-align: right;">Page 195</p> <p>1 Q. What other pore size do you</p> <p>2 think matters?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. Well, I'm forming my opinion</p> <p>5 based on what has been used and what works</p> <p>6 and what I've seen in my clinical practice.</p> <p>7 So not just on the pore size.</p> <p>8 BY MR. FAES:</p> <p>9 Q. But regard -- with regard to</p> <p>10 the pore size which is needed for proper</p> <p>11 tissue integration, is the only guideline</p> <p>12 that you are relying on 75 microns?</p> <p>13 A. That's the main thing I'm</p> <p>14 relying on because I think that's what the</p> <p>15 majority of pelvic floor science relies on.</p> <p>16 Q. Is there any other numerical or</p> <p>17 quantitative guideline that you're relying on</p> <p>18 for the size the pores need to be in the mesh</p> <p>19 in order for proper tissue integration?</p> <p>20 A. Not that I can think of right</p> <p>21 now.</p> <p>22 Q. Have you ever specifically</p> <p>23 studied the question of whether or not a</p> <p>24 1-millimeter pore size under strain is of any</p>	<p style="text-align: right;">Page 197</p> <p>1 some follow-up questions, but I think you</p> <p>2 answered the question.</p> <p>3 A. Okay.</p> <p>4 Q. Would you agree that even if</p> <p>5 the Prosima or Prolift device is placed</p> <p>6 perfectly by the surgeon, that the pore sizes</p> <p>7 can still become deformed or stretch or be</p> <p>8 put under strain?</p> <p>9 A. Yes, they can.</p> <p>10 Q. Does the -- do you know if the</p> <p>11 term "scar plating" had any significance for</p> <p>12 Ethicon internally among doctors and</p> <p>13 scientists?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I don't know.</p> <p>16 BY MR. FAES:</p> <p>17 Q. Would you agree that when the</p> <p>18 mesh goes through the process of creating</p> <p>19 scar tissue and fibrosis on the mesh, those</p> <p>20 processes can also be accompanied by</p> <p>21 contraction of the mesh?</p> <p>22 MR. GAGE: Object to form.</p> <p>23 A. It's designed to have fibrosis</p> <p>24 and scarring to incorporate the mesh and</p>
<p style="text-align: right;">Page 196</p> <p>1 significance with the Prosima, Gynemesh PS or</p> <p>2 Prolift devices?</p> <p>3 A. Did you say "under strain"?</p> <p>4 Q. Yeah, I'll re-ask the question.</p> <p>5 Have you ever specifically studied the</p> <p>6 question of whether or not a 1-millimeter</p> <p>7 pore size under strain is of any significance</p> <p>8 with the Prosima, Gynemesh PS or Prolift</p> <p>9 devices?</p> <p>10 A. What do you mean by "under</p> <p>11 strain"?</p> <p>12 Q. I mean when the mesh is put --</p> <p>13 placed under stress or deforms.</p> <p>14 A. I believe I did look at some</p> <p>15 articles that look at that and look at the --</p> <p>16 what happens to the pore sizes when they are</p> <p>17 under strain. Whether that applies to</p> <p>18 clinical practice or not, I don't think so.</p> <p>19 There's going to a little bit of strain and</p> <p>20 deforming, but if the mesh is placed properly</p> <p>21 without tension, then the pore sizes will be</p> <p>22 minimally deformed. Does that answer your</p> <p>23 question?</p> <p>24 Q. Yeah, I think so. Might have</p>	<p style="text-align: right;">Page 198</p> <p>1 you'll have some mesh contraction, but again,</p> <p>2 I dispute the term "mesh" -- you'll have scar</p> <p>3 contraction, but I dispute the term "mesh</p> <p>4 contraction."</p> <p>5 BY MR. FAES:</p> <p>6 Q. So you dispute the term "mesh</p> <p>7 contraction" even though the Gynemesh PS IFU</p> <p>8 specifically warns excessive contraction or</p> <p>9 shrinkage of the tissue surrounding the mesh</p> <p>10 as a potential adverse event in the</p> <p>11 Gynemesh PS?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. It says -- again, it says,</p> <p>14 "Excessive contraction or shrinkage of the</p> <p>15 tissue surrounding the mesh." I think that's</p> <p>16 the same thing that I said.</p> <p>17 BY MR. FAES:</p> <p>18 Q. But we -- as we've agreed, if</p> <p>19 the tissue surrounding the mesh contracts, it</p> <p>20 can take the mesh with it --</p> <p>21 A. Yes.</p> <p>22 Q. -- meaning the mesh can</p> <p>23 contract as well.</p> <p>24 A. It's semantics. Yes, the mesh</p>

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<p>1 can be incorporated into the scar tissue, but</p> <p>2 the mesh itself is not contracting.</p> <p>3 Q. Do you know who the inventor of</p> <p>4 the Prosima device is?</p> <p>5 A. I believe it was Dr. Marcus</p> <p>6 Carey.</p> <p>7 Q. Have you ever met Dr. Carey?</p> <p>8 A. I don't think so.</p> <p>9 Q. Do you know that -- whether or</p> <p>10 not Dr. Carey receives royalties each time</p> <p>11 the Prosima device is sold?</p> <p>12 A. I don't know.</p> <p>13 Q. So I take it since you don't</p> <p>14 know whether or not he receives royalties,</p> <p>15 you don't know how much he's been paid in</p> <p>16 royalties with regard to the Prosima?</p> <p>17 A. No. But he should get paid</p> <p>18 because it's a great invention. He should</p> <p>19 get paid for his intellectual knowledge --</p> <p>20 his intellectual property, I should say.</p> <p>21 MR. FAES: Object and move to</p> <p>22 strike after the answer "no."</p> <p>23 BY MR. FAES:</p> <p>24 Q. Do you know if he's been paid</p>	<p>1 Q. Do you know that some other</p> <p>2 investigators in that study reported a zero</p> <p>3 percent success rate with the Prosima at</p> <p>4 their site?</p> <p>5 A. No, I'm not aware of that.</p> <p>6 Q. Do you think the fact that</p> <p>7 Dr. Carey was the inventor of the product and</p> <p>8 was going to receive royalties for each</p> <p>9 Prosima device that he sold injected bias</p> <p>10 into the study where he was the lead</p> <p>11 investigator?</p> <p>12 A. I think every investigator has</p> <p>13 a bias. So, yes, of course, he's going to</p> <p>14 have his own bias.</p> <p>15 Q. Do you know whether or not</p> <p>16 Ethicon believed that there was a fair amount</p> <p>17 of spin going on regarding Dr. Carey's</p> <p>18 reporting of his data?</p> <p>19 A. I don't know.</p> <p>20 MR. GAGE: Object to form.</p> <p>21 BY MR. FAES:</p> <p>22 Q. Have you ever seen any</p> <p>23 documents or correspondence between Ethicon</p> <p>24 indicating that that was the case?</p>
Page 200	Page 202
<p>1 over \$2 million in royalties for the Prosima</p> <p>2 device?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. I don't know.</p> <p>5 BY MR. FAES:</p> <p>6 Q. Do you know he was the lead</p> <p>7 author on the Prosima study done by Ethicon</p> <p>8 prior to launch?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know what his personal</p> <p>11 success rate that he reported with the</p> <p>12 Prosima was in that clinical study at his</p> <p>13 site?</p> <p>14 A. At his site alone?</p> <p>15 Q. Yes.</p> <p>16 A. No, I don't know.</p> <p>17 Q. Do you know if it was</p> <p>18 100 percent? Would that -- would you be</p> <p>19 surprised to learn that he -- strike that.</p> <p>20 Would you be surprised to learn</p> <p>21 that Dr. Carey reported a 100 percent success</p> <p>22 rate with the Prosima at his site?</p> <p>23 A. No. It could be possible based</p> <p>24 on patient selection.</p>	<p>1 A. I don't recall having seen</p> <p>2 that.</p> <p>3 Q. Now, you've stated that you</p> <p>4 don't believe that shrinkage of the mesh</p> <p>5 occurs; it's contraction of the tissues</p> <p>6 surrounding the mesh, correct?</p> <p>7 A. Correct.</p> <p>8 Q. Are you familiar with the</p> <p>9 Fatton article, which I believe is cited in</p> <p>10 your reliance materials?</p> <p>11 A. How are you spelling that?</p> <p>12 Q. F-a-t-t-o-n.</p> <p>13 A. I would have to review it</p> <p>14 again. Not off the top of my head.</p> <p>15 Q. Well, let me ask you this. Do</p> <p>16 you recall in that study that they reported a</p> <p>17 17 percent shrinkage rate at three months?</p> <p>18 A. I would have to look at it.</p> <p>19 Q. So you don't recall as you sit</p> <p>20 here today?</p> <p>21 A. I don't recall.</p> <p>22 Q. Would you agree that --</p> <p>23 assuming they did report a 17 percent</p> <p>24 shrinkage rate at three months, that that's a</p>

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<p style="text-align: right;">Page 203</p> <p>1 significant shrinkage rate?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I would say that that is within</p> <p>4 the norm for pelvic surgery to have</p> <p>5 17 percent shrinkage of the scar tissue. You</p> <p>6 would want to have some shrinkage of the scar</p> <p>7 tissue in order to have a good repair. And</p> <p>8 17 percent sounds reasonable to me.</p> <p>9 BY MR. FAES:</p> <p>10 Q. But would you agree that a</p> <p>11 17 percent shrinkage rate is clinically</p> <p>12 significant and could have clinical impact to</p> <p>13 the patient?</p> <p>14 A. Yes, I think it would have a</p> <p>15 good clinical impact because they're going to</p> <p>16 have better support and -- better support of</p> <p>17 the vaginal wall.</p> <p>18 Q. So you believe that -- do you</p> <p>19 believe that shrinkage of the mesh or</p> <p>20 contraction of the tissue surrounding the</p> <p>21 mesh is a positive thing?</p> <p>22 A. Yes. It's desirable.</p> <p>23 Q. Do you believe that's true in</p> <p>24 all cases, or do you believe that there's</p>	<p style="text-align: right;">Page 205</p> <p>1 through things.</p> <p>2 Q. Have you relied on data and</p> <p>3 literature published by Dr. Cosson and the</p> <p>4 TVM group to support your opinions that the</p> <p>5 Prolift and Gynemesh PS is safe and</p> <p>6 effective?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know whether or not</p> <p>9 Dr. Cosson is considered the inventor of the</p> <p>10 Prolift?</p> <p>11 A. I believe he is.</p> <p>12 Q. Have you ever met Dr. Cosson?</p> <p>13 A. No.</p> <p>14 Q. Never been to France?</p> <p>15 A. No.</p> <p>16 Q. Do you know if Dr. Cosson</p> <p>17 receives royalty on the Prolift like</p> <p>18 Dr. Carey?</p> <p>19 A. I don't know.</p> <p>20 Q. Do you know if Dr. Cosson has</p> <p>21 also received over \$2 million in royalties</p> <p>22 for the Prolift device?</p> <p>23 A. I don't know.</p> <p>24 Q. Would you agree that the fact</p>
<p style="text-align: right;">Page 204</p> <p>1 instances where contraction or shrinkage of</p> <p>2 the mesh can cause pain or can cause the</p> <p>3 device to migrate?</p> <p>4 A. Oh, yes, I think it's clear</p> <p>5 that you're going to have some patients that</p> <p>6 heal with exuberant scar tissue, nerve</p> <p>7 endings get involved and they would have more</p> <p>8 pain. That can also occur with plication or</p> <p>9 sacrospinous ligament fixation or uterosacral</p> <p>10 ligament fixation, so it's not unique to</p> <p>11 mesh.</p> <p>12 MR. FAES: I'm going to object</p> <p>13 and move to strike after the answer</p> <p>14 ending with "pain." I didn't ask</p> <p>15 about plication or sacrospinous</p> <p>16 ligament fixation or any of that.</p> <p>17 BY MR. FAES:</p> <p>18 Q. Are you aware of any clinical</p> <p>19 data reported by the French transvaginal mesh</p> <p>20 group regarding the percentage of women</p> <p>21 treated with Prolift suffering from painful</p> <p>22 mesh contraction with the Prolift?</p> <p>23 A. I believe I've seen that. I</p> <p>24 can't cite it right now without looking</p>	<p style="text-align: right;">Page 206</p> <p>1 that Dr. Cosson was the inventor and received</p> <p>2 royalties, that that would inject potential</p> <p>3 bias into any study he was involved in?</p> <p>4 A. I would give the same answer</p> <p>5 before, that every investigator has some bias</p> <p>6 to some degree. So I would not be surprised</p> <p>7 if there were some bias there.</p> <p>8 Q. So is the answer to my question</p> <p>9 yes, you would agree that Dr. Cosson would</p> <p>10 have potential bias in any reporting of any</p> <p>11 studies that he was involved in with the</p> <p>12 Prolift?</p> <p>13 A. Yes, there's a potential for</p> <p>14 bias there.</p> <p>15 Q. Are you familiar with committee</p> <p>16 opinion 513, the joint opinion of ACOG and</p> <p>17 AUGS?</p> <p>18 A. Can I take a look at it?</p> <p>19 Q. I don't have -- I don't have a</p> <p>20 copy with me here. I'm just asking you, are</p> <p>21 you familiar with it?</p> <p>22 A. I don't know of one by name --</p> <p>23 by that name.</p> <p>24 Q. Okay. Well, I'll represent to</p>

18 (Pages 203 to 206)

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<p style="text-align: right;">Page 207</p> <p>1 you that a portion of the committee opinion 2 said that the mesh kit should only be used in 3 high -- strike that. 4 I'll represent to you that a 5 portion of the committee opinion says that 6 mesh kits should only be used in high-risk 7 individuals for which no other options are 8 available or appropriate. 9 Do you agree or disagree with 10 that opinion? 11 MR. GAGE: Object to form. 12 A. At this point I would agree, 13 given the current legal environment, I think, 14 although we had great success in patients 15 that weren't as high risk or that was their 16 first option. But unfortunately in this 17 current legal environment, I would have to 18 agree with that statement. 19 BY MR. FAES: 20 Q. You say "in this current 21 environment." At what point do you 22 believe -- strike that. 23 You indicated -- is there -- 24 strike that too.</p>	<p style="text-align: right;">Page 209</p> <p>1 judgment, you disagree with that opinion? 2 A. Right. Based on my medical 3 judgment, I still think that transvaginal 4 mesh repairs are very effective, very safe 5 and very beneficial to women, even if they're 6 not high risk, even if they haven't failed a 7 prior procedure. And that's based on the 8 literature and based on my own experience. 9 Q. Is the -- as you called it, the 10 legal environment the only reason why you 11 agree with that opinion today? 12 A. Yes. 13 Q. So the recent FDA actions and 14 reclassifying pelvic organ prolapse products 15 to a class III high-risk device and issuing a 16 public health notification in 2008 and 2011 17 have no bearing on that opinion? 18 A. No. 19 Q. Do you agree that the Prolift 20 should only be used in women for whom other 21 approaches and other alternative approaches 22 are not reasonable? I think I asked a bad 23 question. I'm going to strike that and 24 re-ask it.</p>
<p style="text-align: right;">Page 208</p> <p>1 Is there a point at which you 2 would not have agreed with that opinion, a 3 point in time, and when did that -- when did 4 your opinion change that you agree with the 5 opinion? 6 A. Probably around the time that 7 there started to be a lot of attorney 8 advertising, soliciting patients, that 9 created a negative environment around mesh 10 surgery. So I think that was 2012, somewhere 11 around there. 12 Q. So up until 2012 you would have 13 disagreed with that opinion; is that 14 accurate? 15 A. That's correct. 16 Q. And after 2012 you agree with 17 that opinion? 18 A. To a degree, yes. 19 Q. Is it your testimony that you 20 only agree with that opinion now because of 21 the legal environment? 22 A. That's correct. 23 Q. So it's not based on medical 24 judgment on your -- based on your medical</p>	<p style="text-align: right;">Page 210</p> <p>1 Do you agree that the Prolift 2 should only be used in women for whom other 3 alternative approaches are not reasonable? 4 MR. GAGE: Object to form. 5 A. Well, the Prolift isn't 6 available anymore, so I'm not sure how to 7 answer that question. 8 BY MR. FAES: 9 Q. When the Prolift was available, 10 would you agree that it should have only been 11 used in women for whom other alternative 12 approaches are not reasonable? 13 A. No. 14 Q. Same question on the Prosima? 15 A. No. I feel like I was asked a 16 lot of these questions before in the Prolift 17 deposition. 18 Q. You've stated some questions -- 19 stated some opinions about the current legal 20 environment regarding mesh devices and 21 products. Do you know how many mesh lawsuits 22 have been filed in the United States at this 23 point? 24 A. I don't know the number.</p>

19 (Pages 207 to 210)



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<p style="text-align: right;">Page 211</p> <p>1 Q. Do you believe that all of the</p> <p>2 mesh suits filed in this country are</p> <p>3 unfounded?</p> <p>4 A. That all of them are unfounded?</p> <p>5 Well, based on the claims of mesh defect and</p> <p>6 failure to warn, I would say yes because</p> <p>7 there's not a mesh defect; there's not a</p> <p>8 failure to warn.</p> <p>9 Q. So if there were over 70,000</p> <p>10 individuals in the United States that had</p> <p>11 filed legal claims against the manufacturers</p> <p>12 of mesh products, you believe that all of</p> <p>13 those claims are unfounded?</p> <p>14 A. Based on the claims, yes.</p> <p>15 Q. Do you -- you would agree that</p> <p>16 the Prosima device is supposed to be placed</p> <p>17 without tension; is that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. Do you know what Ethicon</p> <p>20 thought as to whether or not most doctors</p> <p>21 understood the tension-free concept in</p> <p>22 connection with the Prosima?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 A. No, I don't know what they</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Let me ask a different</p> <p>2 question. Would you agree that if the</p> <p>3 tension-free concept was not understood and</p> <p>4 mesh ended up under tension after completion</p> <p>5 of the Prosima procedure, that could increase</p> <p>6 the risk of complications, correct?</p> <p>7 A. That could, yes.</p> <p>8 Q. Could it increase the risk of</p> <p>9 treatment failure?</p> <p>10 A. No. I think the risk that I</p> <p>11 think of is potentially pulling on the tissue</p> <p>12 and the scarring pulling and causing pain.</p> <p>13 That's the issue I think of with tension.</p> <p>14 Q. Would you agree that even if a</p> <p>15 doctor is fully trained and follows the</p> <p>16 Prosima technique perfectly, he can end up</p> <p>17 with tension on the mesh that can lead to</p> <p>18 complications?</p> <p>19 A. That -- yes, that can occur.</p> <p>20 The patient can wake up and cough and that</p> <p>21 can pull things, or the way that they heal,</p> <p>22 they have exuberant scar tissue and that can</p> <p>23 cause tension.</p> <p>24 Q. Are you aware of any monograph</p>
<p style="text-align: right;">Page 212</p> <p>1 thought.</p> <p>2 BY MR. FAES:</p> <p>3 Q. Do you know what Ethicon</p> <p>4 thought as to whether or not most doctors</p> <p>5 understood the vaginal support device concept</p> <p>6 in connection with the Prosima?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. No, I don't know what they</p> <p>9 thought.</p> <p>10 BY MR. FAES:</p> <p>11 Q. And you don't know whether or</p> <p>12 not most doctors understood it or not; is</p> <p>13 that correct?</p> <p>14 A. Right, I couldn't comment on</p> <p>15 that.</p> <p>16 Q. You would agree that if the</p> <p>17 tension-free concept with the Prosima was not</p> <p>18 understood and mesh ended up under tension</p> <p>19 after the procedure, that could increase the</p> <p>20 risk of erosions, right?</p> <p>21 A. No, I wouldn't say that. I</p> <p>22 don't think that that would cause erosion.</p> <p>23 Erosion occurs when the mesh is not placed in</p> <p>24 the proper plane.</p>	<p style="text-align: right;">Page 214</p> <p>1 for the Prosima device like there is for the</p> <p>2 Prolift device?</p> <p>3 A. I can't recall if I have seen</p> <p>4 that or not.</p> <p>5 Q. Same question with regard to</p> <p>6 the Gynemesh PS. Is there a Gynemesh PS</p> <p>7 surgeon resource monograph like there is for</p> <p>8 the Prolift and TVT?</p> <p>9 A. I can't recall.</p> <p>10 Q. But there is professional</p> <p>11 education materials for the Prosima device,</p> <p>12 correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Do you recall if there's</p> <p>15 professional education materials for the</p> <p>16 Gynemesh PS device?</p> <p>17 A. Not that I'm aware of.</p> <p>18 Q. Is it your opinion that a</p> <p>19 monograph or professional education materials</p> <p>20 can be a substitute for the IFU in providing</p> <p>21 information about risks and complications to</p> <p>22 physicians?</p> <p>23 A. Yes, I believe so.</p> <p>24 Q. Do you know if -- under the</p>

20 (Pages 211 to 214)



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<p style="text-align: right;">Page 215</p> <p>1 federal rules or regulatory guidance if  2 Ethicon is allowed to provide that kind of  3 information in a source other than the IFU  4 such as a monograph or professional education  5 materials?  6 A. I don't know about that.  7 Q. Would you agree that unlike the  8 IFU, Ethicon can't ensure that the monographs  9 or the professional education materials reach  10 every physician that uses the product?  11 MR. GAGE: Object to form.  12 A. Can you repeat that question,  13 please.  14 BY MR. FAES:  15 Q. Would you agree that unlike the  16 IFU, Ethicon has no way of ensuring that  17 monographs or professional education  18 materials reach every physician that uses the  19 product?  20 A. I don't think they can ensure  21 that the IFU reaches every physician. Sure,  22 it's in every product, but that doesn't mean  23 that every physician does look at it or read  24 it.</p>	<p style="text-align: right;">Page 217</p> <p>1 Q. Once an IFU is out there, if  2 Ethicon learns of a risk or complication that  3 was not previously warned about and it was a  4 significant risk or complication in terms of  5 the harm it could cause to a woman, do you  6 know whether or not Ethicon had any  7 obligation to get that out to doctors?  8 A. Could you repeat that, please.  9 Q. Sure. Once an IFU is out  10 there, if Ethicon learns of a risk or  11 complication that was not previously warned  12 about and it's a significant risk or  13 complication in terms of the harm it could  14 cause to a woman, do you know whether or not  15 Ethicon had any obligation to get that out to  16 doctors?  17 MR. GAGE: Object to form.  18 A. I don't know.  19 BY MR. FAES:  20 Q. I just want to backtrack a  21 little bit on the IFU -- the 2015 Gynemesh  22 IFU that was put out there.  23 Do you think it would have been  24 reasonable for Ethicon to send a letter, a</p>
<p style="text-align: right;">Page 216</p> <p>1 Q. But by placing the IFU in the  2 box, Ethicon ensures that every physician has  3 at least access to the IFU, correct?  4 A. Yes, I can agree with that.  5 Q. If Ethicon had put the same  6 information that's in the monograph in their  7 professional education materials in the IFU  8 with regards to the risks of the device, they  9 could have ensured that every physician who  10 implants the device at least has access to  11 that information, correct?  12 A. I'm sorry, can you repeat the  13 question?  14 Q. If Ethicon had put the same  15 information in the monograph -- strike that.  16 If Ethicon had put the same  17 information that's in the monograph and  18 professional educations in their IFU with  19 regard to the risks and adverse reactions of  20 the device, they could have ensured that  21 every physician who implants the device at  22 least has access to that information,  23 correct?  24 A. Sure.</p>	<p style="text-align: right;">Page 218</p> <p>1 "Dear Doctor" letter out to physicians when  2 they put that IFU out telling them that, hey,  3 we've added some adverse reactions to this  4 IFU that were not previously in the IFU?  5 A. Sure, I think that's  6 reasonable. I don't think it's necessary,  7 but it's reasonable.  8 Q. Do you know whether or not that  9 occurred?  10 A. I don't know.  11 Q. Do you think it would have been  12 reasonable in 2013 for Ethicon to send a  13 letter out to physicians that -- informing  14 them that, hey, we've changed the indications  15 for use for this mesh so that it is no longer  16 indicated for transvaginal mesh placement?  17 Do you think that would be reasonable?  18 A. Sure, I think it's reasonable.  19 Q. Do you think it would have been  20 reasonable for them in this letter to also  21 tell physicians that the only reason that the  22 FDA is still allowing this product to be sold  23 is because it agreed to remove the  24 transvaginal indication and change the</p>

21 (Pages 215 to 218)

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<p style="text-align: right;">Page 219</p> <p>1 indication to only be placed abdominally?</p> <p>2 MR. GAGE: Object to form.</p> <p>3 A. I don't think that's reasonable</p> <p>4 or necessary. That sounds excessive to me.</p> <p>5 BY MR. FAES:</p> <p>6 Q. You don't think a reasonable</p> <p>7 physician would want to know that the only</p> <p>8 reason the FDA is still allowing the</p> <p>9 Gynemesh PS to be sold is because Ethicon</p> <p>10 agreed to remove the transvaginal use</p> <p>11 indication from the IFU?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 A. I don't think so.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Do you know whether or not</p> <p>16 Ethicon did indeed send out a letter to</p> <p>17 physicians informing them that the</p> <p>18 indications for use for the Gynemesh PS</p> <p>19 device changed?</p> <p>20 A. I don't know.</p> <p>21 Q. Do you think it would be</p> <p>22 reasonable for Ethicon to put some kind of an</p> <p>23 indication on the Gynemesh PS box that</p> <p>24 contains the device either with a call-out on</p>	<p style="text-align: right;">Page 221</p> <p>1 would be a mistake to launch the device onto</p> <p>2 the market, do you think it would be wrongful</p> <p>3 for the company to launch that device anyway</p> <p>4 if the motivation is only to make a profit?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 A. Can you repeat that question,</p> <p>7 please.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Sure. If the overall consensus</p> <p>10 among a medical device company's expert is</p> <p>11 that it would be a mistake to launch that</p> <p>12 device onto the market, do you think it would</p> <p>13 be wrongful for the company to launch that</p> <p>14 device anyway if the only motivation is to</p> <p>15 make a profit?</p> <p>16 MR. GAGE: Object to form.</p> <p>17 A. Well, it depends on why they</p> <p>18 think it's a mistake. I mean, obviously the</p> <p>19 purpose of corporations is they have to make</p> <p>20 a profit with whatever they do. So it</p> <p>21 depends on what the -- why -- what they're --</p> <p>22 why they're saying it's a mistake.</p> <p>23 BY MR. FAES:</p> <p>24 Q. If the company's experts</p>
<p style="text-align: right;">Page 220</p> <p>1 the box or a sticker informing physicians</p> <p>2 that, hey, the indications for this use have</p> <p>3 changed; you might want to read them? Do you</p> <p>4 think that would be reasonable?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 A. Again, I think it's reasonable,</p> <p>7 but it's not necessary.</p> <p>8 BY MR. FAES:</p> <p>9 Q. So even though that you -- even</p> <p>10 though you've testified that you don't</p> <p>11 generally review the IFU, again, once you've</p> <p>12 used a product for the first time, you don't</p> <p>13 believe it's necessary?</p> <p>14 A. Correct.</p> <p>15 Q. You don't think that that's</p> <p>16 something that physicians would want to know</p> <p>17 or have their attention drawn to, that, hey,</p> <p>18 the indications for this device may have</p> <p>19 changed since the last time you used it?</p> <p>20 A. I can -- I can't speak for all</p> <p>21 physicians. I'm speaking for myself. That</p> <p>22 for me, it wouldn't be necessary.</p> <p>23 Q. If the overall consensus among</p> <p>24 a medical devices company's expert is that it</p>	<p style="text-align: right;">Page 222</p> <p>1 believe it's a mistake to launch that</p> <p>2 particular device on the market because it is</p> <p>3 not more safe or effective than alternative</p> <p>4 treatment options, do you think it would be</p> <p>5 wrongful for the company to launch that</p> <p>6 device anyway?</p> <p>7 A. I can't answer that yes or no.</p> <p>8 It really depends on the details of the</p> <p>9 product. There may be some other advantages,</p> <p>10 some other factors involved.</p> <p>11 Q. If the overall consensus about</p> <p>12 a medical device -- strike that.</p> <p>13 If the overall consensus among</p> <p>14 the medical device company's experts is that</p> <p>15 it would be a mistake to launch a particular</p> <p>16 device onto the market, do you think the</p> <p>17 doctors and patients who are sold that device</p> <p>18 should know that information?</p> <p>19 A. I think it's more -- no,</p> <p>20 because I think it's more important that</p> <p>21 there's data showing the results, that</p> <p>22 there's studies that show the results of what</p> <p>23 happened and not their -- just those</p> <p>24 opinions.</p>

22 (Pages 219 to 222)

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<p style="text-align: right;">Page 223</p> <p>1 Q. So you don't think that that's</p> <p>2 information that doctors or patients would</p> <p>3 want to know, is that the company had asked</p> <p>4 their experts what they thought about the</p> <p>5 device and the experts told the company, this</p> <p>6 is a big mistake, don't do it?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 A. I don't know what other doctors</p> <p>9 and patients would want to know.</p> <p>10 BY MR. FAES:</p> <p>11 Q. Do you know whether scar</p> <p>12 contracture around the mesh can occur with</p> <p>13 the Gynemesh PS?</p> <p>14 A. Yes, it can. As in every</p> <p>15 pelvic surgery, there's going to be scar</p> <p>16 contracture if you just cut on the vagina.</p> <p>17 MR. FAES: Object and move to</p> <p>18 strike after the answer "yes, it can."</p> <p>19 BY MR. FAES:</p> <p>20 Q. Do you know whether or not that</p> <p>21 was a problem that Ethicon's engineers were</p> <p>22 trying to solve by designing a better mesh?</p> <p>23 A. I don't recall.</p> <p>24 Q. Would you agree that scar</p>	<p style="text-align: right;">Page 225</p> <p>1 A. Yes, it can do that with or</p> <p>2 without mesh.</p> <p>3 MR. FAES: Object and move to</p> <p>4 strike after the answer "yes."</p> <p>5 BY MR. FAES:</p> <p>6 Q. Would you agree that scar</p> <p>7 contracture can cause erosion?</p> <p>8 A. No.</p> <p>9 Q. Would you agree that scar</p> <p>10 contracture can cause discomfort during sex?</p> <p>11 A. Yes. That can occur with or</p> <p>12 without the presence of mesh.</p> <p>13 MR. FAES: Object and move to</p> <p>14 strike after the answer "yes."</p> <p>15 BY MR. FAES:</p> <p>16 Q. So you disagree that scar</p> <p>17 contracture can cause recurrence of the</p> <p>18 prolapse or erosion, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So if physicians were reporting</p> <p>21 to Ethicon that scar contracture can cause</p> <p>22 recurrence of the prolapse and erosion, you</p> <p>23 would disagree with those physicians?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 224</p> <p>1 contracture can translate into procedural</p> <p>2 complications?</p> <p>3 A. Yes, it can.</p> <p>4 Q. Do you know whether or not in</p> <p>5 2005, physicians were asking Ethicon for a</p> <p>6 mesh which would be better than the</p> <p>7 Gynemesh PS in the area of scar contracture?</p> <p>8 A. I don't know.</p> <p>9 Q. Would you agree that scar</p> <p>10 contracture can cause recurrence of prolapse?</p> <p>11 A. No, I disagree with that.</p> <p>12 Q. Would you agree that scar</p> <p>13 contracture can cause pain?</p> <p>14 A. Yes, I agree with that.</p> <p>15 Q. Would you agree that scar</p> <p>16 contracture can cause stiffness?</p> <p>17 A. Stiffness?</p> <p>18 Q. Yes. Stiffness of the mesh.</p> <p>19 I'll rephrase. Would you agree that scar</p> <p>20 contracture can cause stiffness of the mesh?</p> <p>21 A. No, I don't think it causes</p> <p>22 stiffness of the mesh.</p> <p>23 Q. Would you agree that scar</p> <p>24 contracture can cause a stiff scar tissue?</p>	<p style="text-align: right;">Page 226</p> <p>1 Q. Would you agree that for mesh</p> <p>2 to be successfully used for the treatment of</p> <p>3 pelvic organ prolapse, it should be soft and</p> <p>4 compliant with a woman's vaginal tissues?</p> <p>5 A. Ideally, yes.</p> <p>6 Q. Would you agree that a mesh</p> <p>7 could be too stiff for the treatment of</p> <p>8 pelvic organ prolapse?</p> <p>9 A. Yes, it's possible.</p> <p>10 MR. FAES: Can we go off the</p> <p>11 record for a quick second.</p> <p>12 (Recess Taken From 10:00 a.m.</p> <p>13 To 10:09 a.m.)</p> <p>14 BY MR. FAES:</p> <p>15 Q. Dr. Pramudji, we're back on the</p> <p>16 record after a short break. Are you ready to</p> <p>17 proceed?</p> <p>18 A. Yes.</p> <p>19 Q. You know that the Gynemesh PS</p> <p>20 is, in fact, less stiff than the traditional</p> <p>21 Prolene mesh used for hernia repairs,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. And, in fact, that's a positive</p>

23 (Pages 223 to 226)

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<p style="text-align: right;">Page 227</p> <p>1 thing --</p> <p>2 A. Yes.</p> <p>3 Q. -- you would agree --</p> <p>4 A. Yes.</p> <p>5 Q. -- for use in vaginal tissues,</p> <p>6 correct?</p> <p>7 A. Yes, I agree.</p> <p>8 Q. Have you ever considered using</p> <p>9 traditional Prolene mesh for the treatment of</p> <p>10 pelvic organ prolapse?</p> <p>11 A. No.</p> <p>12 Q. Have you ever considered using</p> <p>13 traditional Prolene mesh for use in vaginal</p> <p>14 tissues?</p> <p>15 A. No.</p> <p>16 Q. Would you ever consider using</p> <p>17 it?</p> <p>18 A. I don't think so.</p> <p>19 Q. Would you never -- not consider</p> <p>20 using it because it's generally too stiff to</p> <p>21 be compliant with vaginal tissues?</p> <p>22 A. That's correct.</p> <p>23 Q. Would you agree that clinically</p> <p>24 there may be an impact with increased</p>	<p style="text-align: right;">Page 229</p> <p>1 Gynemesh PS is an appropriate stiffness of</p> <p>2 mesh, but I wouldn't disagree with trying to</p> <p>3 make a less stiff mesh and see if it</p> <p>4 behaved -- if the results are as good.</p> <p>5 Q. Do you know whether or not, as</p> <p>6 of 2009, it was Ethicon's goal that all</p> <p>7 future meshes developed by Ethicon for pelvic</p> <p>8 organ prolapse should be less rigid than the</p> <p>9 Gynemesh PS?</p> <p>10 MR. GAGE: Object to form.</p> <p>11 A. I don't know.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Would you agree that clinical</p> <p>14 trials show that large-pore meshes in general</p> <p>15 provide better patient comfort than standard</p> <p>16 meshes?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 BY MR. FAES:</p> <p>19 Q. Strike that. I'm going to</p> <p>20 withdraw that and ask a different question.</p> <p>21 Would you agree that clinical</p> <p>22 trials show in general that large-pore meshes</p> <p>23 provide better patient comfort than standard</p> <p>24 meshes and that the reason for that is due to</p>
<p style="text-align: right;">Page 228</p> <p>1 rigidity with any given mesh as it may</p> <p>2 increase vaginal stiffness postoperatively</p> <p>3 with a potential to impair sexual function?</p> <p>4 A. Could you repeat that, please.</p> <p>5 Q. Sure. Would you agree that</p> <p>6 clinically there may be an impact of</p> <p>7 increased rigidity with any given mesh as it</p> <p>8 may increase vaginal stiffness</p> <p>9 postoperatively with a potential to impair</p> <p>10 sexual function?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 A. That could occur with some</p> <p>13 meshes that are more stiff.</p> <p>14 BY MR. FAES:</p> <p>15 Q. Would you agree that any future</p> <p>16 meshes developed by Ethicon for the treatment</p> <p>17 of pelvic organ prolapse should be less rigid</p> <p>18 than the Gynemesh PS?</p> <p>19 A. No, I don't agree with that.</p> <p>20 Q. So if Ethicon's medical</p> <p>21 directors believe that that was an</p> <p>22 appropriate goal, you would disagree with</p> <p>23 them?</p> <p>24 A. I would say that the</p>	<p style="text-align: right;">Page 230</p> <p>1 lower scar tissue formation and lower</p> <p>2 stiffness?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. What are the standard meshes</p> <p>5 that you're referring to?</p> <p>6 BY MR. FAES:</p> <p>7 Q. A standard mesh would be, for</p> <p>8 example, the standard Prolene mesh or the</p> <p>9 standard Marlex mesh, which is now called the</p> <p>10 Bard mesh.</p> <p>11 A. Okay. I understand. So the</p> <p>12 answer -- you'd better repeat the question so</p> <p>13 I make sure I answer properly.</p> <p>14 Q. Sure. Would you agree that</p> <p>15 clinical trials show that large-pore meshes</p> <p>16 provide better patient comfort than standard</p> <p>17 meshes and the reason is due to lower scar</p> <p>18 tissue formation and lower stiffness?</p> <p>19 A. Yes, that's correct.</p> <p>20 Q. Are you aware that Ethicon was</p> <p>21 told by its top consultants that it didn't</p> <p>22 make sense to use the Prosima in people with</p> <p>23 lesser degrees of prolapse given the</p> <p>24 outcomes?</p>

24 (Pages 227 to 230)

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<p style="text-align: right;">Page 231</p> <p>1 MR. GAGE: Object to form.</p> <p>2 A. I'm not aware of that.</p> <p>3 BY MR. FAES:</p> <p>4 Q. Do you know how the mesh in the</p> <p>5 Prolift is cut?</p> <p>6 A. I believe it's machine cut.</p> <p>7 Q. You believe that the mesh in</p> <p>8 the Prolift is machine cut?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know how the mesh in the</p> <p>11 Prosima is cut?</p> <p>12 A. I believe it's also machine</p> <p>13 cut.</p> <p>14 Q. Do you know how the mesh in the</p> <p>15 Gynemesh PS flat sheets is cut?</p> <p>16 A. Not sure about that one.</p> <p>17 Q. Do you know whether or not the</p> <p>18 cutting method for Prolene mesh affects the</p> <p>19 rigidity or stiffness of the mesh?</p> <p>20 A. It does not.</p> <p>21 Q. So it's your opinion that -- to</p> <p>22 a reasonable degree of medical certainty,</p> <p>23 that the cutting method for the Prolene mesh,</p> <p>24 whether it be mechanical, laser cut or</p>	<p style="text-align: right;">Page 233</p> <p>1 whether it's the Prolift, the Prosima or the</p> <p>2 flat sheets, that there can be sharp edges</p> <p>3 after the mesh is cut?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. No, they're not sharp edges.</p> <p>6 They're floppy fibers.</p> <p>7 BY MR. FAES:</p> <p>8 Q. So you don't believe that there</p> <p>9 can be a sharp edge on the Gynemesh PS mesh</p> <p>10 after it's cut with scissors?</p> <p>11 A. No, no sharper than a suture</p> <p>12 that you would have.</p> <p>13 Q. You don't believe that a</p> <p>14 potential risk -- strike that.</p> <p>15 You don't believe that there</p> <p>16 can be a sharp edge after cutting the</p> <p>17 Gynemesh PS with the scissors and the</p> <p>18 potential risk of that sharp edge is that it</p> <p>19 can cause erosion or pain or protrude through</p> <p>20 the woman's delicate vaginal tissues; is that</p> <p>21 correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And if Ethicon scientists and</p> <p>24 engineers who were assessing the risks of the</p>
<p style="text-align: right;">Page 232</p> <p>1 ultrasonically cut, has no effect on the</p> <p>2 stiffness or rigidity of the mesh?</p> <p>3 A. That's correct.</p> <p>4 Q. Have you seen any studies that</p> <p>5 Ethicon has done with regard to the</p> <p>6 difference in stiffness between</p> <p>7 ultrasonically cut and laser cut mesh?</p> <p>8 A. Not that I can recall, as I sit</p> <p>9 here right now.</p> <p>10 Q. If Ethicon did a study</p> <p>11 comparing ultrasonically cut mesh to laser</p> <p>12 cut mesh and found that one of those meshes</p> <p>13 was stiffer than the other, you would</p> <p>14 disagree with those findings?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. I would -- I would have to look</p> <p>17 at it, but I don't think it would make any</p> <p>18 clinical difference at all, because half the</p> <p>19 time you end up trimming the edges anyway,</p> <p>20 which is where the cut edge is. So it ends</p> <p>21 up being mechanically cut no matter what.</p> <p>22 BY MR. FAES:</p> <p>23 Q. Would you agree that when you</p> <p>24 cut the Gynemesh PS with a pair of scissors,</p>	<p style="text-align: right;">Page 234</p> <p>1 Gynemesh PS mesh found that that was a</p> <p>2 potential risk, you would disagree with them?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 A. Yes, I disagree with them.</p> <p>5 That's not what we see in clinical practice.</p> <p>6 BY MR. FAES:</p> <p>7 Q. If other doctors told Ethicon</p> <p>8 that they were concerned that there was a</p> <p>9 risk of sharp edges after the Gynemesh PS</p> <p>10 mesh was cut that could be sharp and cause</p> <p>11 erosion or pain or complications, you believe</p> <p>12 those doctors are wrong and their fears are</p> <p>13 unfounded?</p> <p>14 MR. GAGE: Object to form.</p> <p>15 A. I'm not sure what they're doing</p> <p>16 or how they're implanting it, but when you</p> <p>17 cut the mesh, the edges are no sharper than</p> <p>18 they were before you cut it. And the mesh</p> <p>19 itself is not going to just start poking</p> <p>20 through. Either it's not placed in the right</p> <p>21 plane or the patient has poor wound healing.</p> <p>22 It doesn't just cut through. It's not like</p> <p>23 that at all. It's soft and floppy.</p> <p>24 BY MR. FAES:</p>

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<p>1 Q. Okay. I'm going to have to</p> <p>2 re-ask that question because I think the</p> <p>3 answer you gave me is a little bit</p> <p>4 different --</p> <p>5 A. Sorry.</p> <p>6 Q. -- than the answer I was</p> <p>7 looking for.</p> <p>8 If other doctors told Ethicon</p> <p>9 that they were concerned about sharp edges in</p> <p>10 the Gynemesh PS after it was cut with the</p> <p>11 scissors and that those sharp edges could</p> <p>12 potentially protrude through vaginal tissue</p> <p>13 and cause pain, do you believe that those</p> <p>14 physicians' fears are unfounded?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 A. Yes, I disagree with those</p> <p>17 physicians.</p> <p>18 BY MR. FAES:</p> <p>19 Q. If those same physicians were</p> <p>20 concerned that particles could be released</p> <p>21 when the Gynemesh PS was cut through</p> <p>22 scissors -- strike that.</p> <p>23 If those physicians were</p> <p>24 concerned that particles could be released</p>	<p>1 products?</p> <p>2 A. No, I don't have a calculated</p> <p>3 numeric rate for my patients.</p> <p>4 Q. Same question with regard to</p> <p>5 complication or erosion or extrusion rates,</p> <p>6 do you intend to offer an opinion in this</p> <p>7 case with regard to a numeric percentage of</p> <p>8 complications or erosions or extrusion rates</p> <p>9 that you've experienced personally?</p> <p>10 A. Perhaps. I have in the past</p> <p>11 calculated reoperation rates, but I can't</p> <p>12 recall right now if it was on Prolift or on</p> <p>13 TVT. I would have to go back and look at my</p> <p>14 operative logs.</p> <p>15 Q. So --</p> <p>16 A. So I may have that rate on --</p> <p>17 Q. Just reoperation rates?</p> <p>18 A. Correct, just reoperation</p> <p>19 rates.</p> <p>20 Q. Not exposure or extrusion</p> <p>21 rates?</p> <p>22 A. Correct.</p> <p>23 Q. Can you tell me how you arrived</p> <p>24 at those reoperation rates?</p>
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<p>1 when the Gynemesh PS was cut with scissors</p> <p>2 and that those particles could become lodged</p> <p>3 in a woman's vaginal tissues and cause</p> <p>4 potential complications, do you believe those</p> <p>5 physicians' fears are unfounded?</p> <p>6 MR. GAGE: Object to form.</p> <p>7 A. Absolutely.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Doctor, are you going to</p> <p>10 offer -- do you plan to offer an opinion in</p> <p>11 this case about your personal success rate</p> <p>12 with the Prosima, Prolift or Gynemesh</p> <p>13 products?</p> <p>14 A. Yes.</p> <p>15 Q. What is the opinion you intend</p> <p>16 to offer about your personal success rate</p> <p>17 with those products?</p> <p>18 A. What I found is that the</p> <p>19 products were very successful with a high</p> <p>20 patient satisfaction with few complications.</p> <p>21 Q. Do you intend to offer a</p> <p>22 numeric success rate --</p> <p>23 A. No, I don't have a --</p> <p>24 Q. -- in conjunction with those</p>	<p>1 A. I took my total number of</p> <p>2 reoperations and my total number of cases and</p> <p>3 just divided it.</p> <p>4 Q. And what --</p> <p>5 A. So it's a rough number.</p> <p>6 Q. And what is the numerator and</p> <p>7 denominator for those?</p> <p>8 A. I don't recall, as I sit here</p> <p>9 right now. I would have to look at it.</p> <p>10 Q. And who did -- who did the</p> <p>11 review?</p> <p>12 A. Myself.</p> <p>13 Q. Is there any documentation</p> <p>14 regarding the review or your findings that</p> <p>15 you used to come up with those rates?</p> <p>16 A. I have an operative log that I</p> <p>17 keep.</p> <p>18 Q. Do you know if that's been</p> <p>19 produced to us in this litigation?</p> <p>20 A. No, I don't believe so.</p> <p>21 MR. FAES: We would ask that</p> <p>22 that would be produced if the doctor</p> <p>23 is going to offer any opinions about</p> <p>24 her reoperation rates at trial.</p>

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<p style="text-align: right;">Page 239</p> <p>1 MR. GAGE: I'll consult with 2 her and let you know what our position 3 is on that. 4 BY MR. FAES: 5 Q. Did you do any kind of analysis 6 of patients that were lost to follow-up? 7 A. No, I did not. 8 Q. What time frame were you using 9 for your reoperation rates to come up with 10 your reoperation rate number for Prolift and 11 Proxima? 12 A. Well, I just -- just from 13 the -- when I started using the products 14 until I did the analysis, however many years 15 that was. I can't remember when I did that 16 analysis. 17 Q. But you can't state a specific 18 year that you started and stopped? 19 A. No, I can't remember right now. 20 Q. But it's fair to say it would 21 go back to when you were working in Dallas in 22 Dr. Anhalt's practice, correct? 23 A. Well, yeah. It wasn't in 24 Dallas. It was here in Houston. But, yes,</p>	<p style="text-align: right;">Page 241</p> <p>1 many reoperations did I do? And this is 2 just -- this isn't even -- this is just like 3 a mesh exposure, mesh explant-type 4 reoperation. It's not comprehensive. 5 Q. Okay. I think you've answered 6 my question on that. 7 I hate to do this to you, but 8 since there's no invoices yet on your 9 case-specific depositions that you're going 10 to be offering opinions on, I need to go 11 through and ask you if you have a rough 12 estimate of the number of hours you've spent 13 on each of your cases. Do you know 14 approximately how many hours you've spent on 15 the Sharon Carpenter case? 16 MR. GAGE: Let me just say, I 17 assume that by doing this that the 18 individual lawyers will not ask the 19 question and that you would agree as 20 liaison counsel that I can say "asked 21 and answered," we don't have to do it 22 during the individual cases? 23 MR. FAES: Well, they might ask 24 more specific questions, like break</p>
<p style="text-align: right;">Page 240</p> <p>1 back to 2005, when I started doing the 2 Prolift, until I did the analysis, because 3 there may have been some complications that 4 were treated after I stopped using the 5 products. But I can't remember when I did 6 that. 7 Q. And if a doctor [sic] needed a 8 reoperation and went to a different doctor 9 other than you, you wouldn't have that 10 information unless the patient shared it with 11 you, correct? 12 A. That's correct. 13 Q. So your reoperation rates that 14 you calculated would exclude any patients 15 that went to other doctors for reoperation 16 that you didn't know about, correct? 17 A. Yes. But kind of what I did in 18 reverse, which this is very rough, but I 19 included patients that came from other 20 doctors in my reoperation rate. So some 21 patients were not my original -- I was not 22 the original implanter. So it's kind of -- 23 it's a very rough analysis. There's just 24 sort of, okay, I did this many implants; how</p>	<p style="text-align: right;">Page 242</p> <p>1 down the amount or whatever, but, 2 yeah, you can certainly object. 3 MR. GAGE: Okay. 4 BY MR. FAES: 5 Q. Do you recall how many hours 6 you've spent on the Sharon Carpenter case? 7 A. I don't recall. 8 Q. Do you recall how many hours 9 you've spent on the Mary Jane Olson case? 10 A. I don't remember. 11 Q. You don't have any kind of 12 estimate, as you sit here today, or any 13 documentation regarding how many hours you've 14 spent on that case? 15 A. I would say maybe 30 to 16 50 hours on each case, let's say. That may 17 be high; that may be low. It depends. Some 18 of them are more complicated than others. 19 Q. So you estimate -- your best 20 estimate, as you sit here today, on all the 21 cases, case-specific cases that you are going 22 to offer opinions on in the next couple of 23 days, is that you spent approximately 30 to 24 50 hours on each of those cases?</p>

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<p>1 A. Uh-huh. Yes.</p> <p>2 Q. And that rate at this point</p> <p>3 that you've charged for those cases is \$600</p> <p>4 an hour for review?</p> <p>5 A. Correct.</p> <p>6 Q. And your deposition testimony</p> <p>7 will be 700 an hour, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And that's the same rate as if</p> <p>10 you get called for trial?</p> <p>11 A. Correct.</p> <p>12 (Deposition Exhibit 14 marked.)</p> <p>13 BY MR. FAES:</p> <p>14 Q. Doctor, I'm going to hand you</p> <p>15 what's been marked as Exhibit No. 14 to your</p> <p>16 deposition.</p> <p>17 (Witness Reviews Document.)</p> <p>18 BY MR. FAES:</p> <p>19 Q. Doctor, this is an e-mail from</p> <p>20 you to Robert Zipfel, Z-i-p-f-e-l, at Ethicon</p> <p>21 responding to a press release regarding the</p> <p>22 launch of the Prolift+M; is that correct?</p> <p>23 A. Correct.</p> <p>24 Q. I'm not going to ask you about</p>	<p>1 that are lighter weight and larger pore than</p> <p>2 the mesh used in the original Prolift device,</p> <p>3 correct?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 A. I think -- you said the pores</p> <p>6 are lighter weight. I don't know if that's</p> <p>7 what you meant to say.</p> <p>8 BY MR. FAES:</p> <p>9 Q. That's not what I meant to say.</p> <p>10 A. Okay.</p> <p>11 Q. I'll re-ask the question. And</p> <p>12 you know that this Prolift+M device uses a</p> <p>13 mesh that has larger pores and is of a</p> <p>14 lighter weight than the mesh used in the</p> <p>15 original Prolift device, correct?</p> <p>16 A. I believe after the Monocryl is</p> <p>17 observed, then it becomes a lighter-weight</p> <p>18 mesh.</p> <p>19 Q. In fact, it becomes almost half</p> <p>20 the weight of the mesh used in the Prolift;</p> <p>21 isn't that correct?</p> <p>22 A. That sounds about right.</p> <p>23 Q. And this Prolift+M device, you</p> <p>24 would agree, did ultimately become your</p>
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<p>1 this whole thing, but if you go down to the</p> <p>2 third paragraph, it says, "This</p> <p>3 lightweight" -- with regard to the Prolift+M,</p> <p>4 it says, "This lightweight polypropylene mesh</p> <p>5 is less dense and has larger pores than</p> <p>6 previous meshes, which could lead to</p> <p>7 decreases in reactive scar formation and a</p> <p>8 reduction in inflammatory response during</p> <p>9 healing. This mesh also has properties that</p> <p>10 help the surgeon place the mesh more easily</p> <p>11 because it resists wrinkling and folding, and</p> <p>12 it has increased longitudinal elasticity</p> <p>13 while maintaining lateral support to ensure</p> <p>14 pliability after surgery. The new design may</p> <p>15 improve vaginal wall compliance and allow for</p> <p>16 better tissue incorporation."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Is this your understanding of</p> <p>20 what Ethicon believed were the potential</p> <p>21 benefits of the Prolift+M device?</p> <p>22 A. Yes, that's my understanding.</p> <p>23 Q. And you know that this</p> <p>24 Prolift+M device uses a mesh that has pores</p>	<p>1 device of choice over the Prolift for the</p> <p>2 treatment of pelvic organ prolapse?</p> <p>3 A. Yes.</p> <p>4 Q. That's all the questions I have</p> <p>5 about that document.</p> <p>6 A. Okay.</p> <p>7 (Deposition Exhibit 15 marked.)</p> <p>8 BY MR. FAES:</p> <p>9 Q. Doctor, I'm going to hand you</p> <p>10 what's been marked as Exhibit No. 15 to your</p> <p>11 deposition.</p> <p>12 A. Okay.</p> <p>13 Q. And I just have a real quick</p> <p>14 question about this. This is a document</p> <p>15 dated February 27th, 2008, titled "Prosima</p> <p>16 Launch Plan." And if you turn to the second</p> <p>17 page under "Southern Region," you see that</p> <p>18 your name is listed as the third name on the</p> <p>19 first column. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Does this document indicate</p> <p>22 that you were one of the initial preceptors</p> <p>23 for the launch of the Prosima device?</p> <p>24 A. It looks like I was targeted</p>

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<p style="text-align: right;">Page 247</p> <p>1 for that, but, honestly, I can't remember the 2 timeline on that. 3 Q. Do you remember if you were one 4 of the initial preceptors for the Prosima 5 device? 6 A. I don't remember. 7 Q. So you could've been or you 8 might not have been; you just don't know one 9 way or the other? 10 A. Yes, I can't remember. 11 Q. That's all the questions I have 12 for that document. 13 (Deposition Exhibit 16 marked.) 14 (Deposition Exhibit 17 marked.) 15 BY MR. FAES: 16 Q. I'm going to hand you what's 17 been marked as Exhibits 16 and 17. 18 Doctor, Exhibit No. 16 is an 19 e-mail dated January 13th, 2009, regarding a 20 urology meeting follow-up. Do you see that? 21 A. Yes. 22 BY MR. FAES: 23 Q. If you turn to the fourth page 24 where it discusses the "Blue Group," you see</p>	<p style="text-align: right;">Page 249</p> <p>1 prolapse? 2 A. Well, this was right after the 3 2008 FDA notification, so that may have been 4 where some of that sentiment came from. But 5 I don't recall specifically any conversations 6 at that conference. 7 Q. My question was actually a 8 little bit different than that. So I'm going 9 to re-ask it. 10 A. Okay. 11 Q. Did you believe, at this time 12 in 2009, that it was important to ease the 13 fears of patients with regard to the safety 14 of mesh devices for the treatment of pelvic 15 organ prolapse? 16 A. I'm sorry, can you repeat that 17 one more time? 18 Q. Did you believe, at this time 19 in 2009, that it was an important goal to 20 ease the fears of patients with regard to the 21 safety of mesh devices for the treatment of 22 pelvic organ prolapse? 23 A. I can't remember what I thought 24 at that time.</p>
<p style="text-align: right;">Page 248</p> <p>1 that you are listed, as the sixth name down, 2 as participating in this group. Do you see 3 that? 4 A. Yes. 5 Q. Do you remember participating 6 in this group in 2009? 7 A. Vaguely. 8 Q. If you look down under 9 "Recommendations to Group: Patient 10 Education," the fourth bullet point down, it 11 states, "Safety long-term communicate to 12 patients, this eases their fears." Do you 13 see that? 14 MR. GAGE: Object to form. 15 A. Yes, I see that. 16 BY MR. FAES: 17 Q. Did you -- was this a 18 recommendation that you remember the team 19 making to Ethicon? 20 A. I don't remember. 21 Q. Did you believe, at this time 22 in 2009, it was important to ease the fears 23 of patients with regard to the safety of mesh 24 devices for the treatment of pelvic organ</p>	<p style="text-align: right;">Page 250</p> <p>1 Q. You see the second bullet point 2 down, it says, "Google - have EWHU" -- which 3 you know stands for "Ethicon Women's Health &amp; 4 Urology," correct? 5 A. Correct. 6 Q. -- "website precede litigation 7 websites." You see that? 8 A. Yes. 9 Q. So one of the recommendations 10 of the team was to pay Google to have 11 Ethicon's website appear before any 12 litigation websites on Google searches? 13 A. That's what it appears to be. 14 Q. Now, you stated that the 15 litigation environment changed in 2012 and 16 that's when you believed that pelvic organ 17 prolapse devices should not be considered for 18 first-line treatment, correct? 19 A. That's when it really seemed to 20 ramp up. 21 Q. But, at least according to this 22 document in 2009, fears about lawsuits were 23 of concern going back to 2009 -- 24 A. That's what it looks like --</p>

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<p>1 Q. -- is that correct?</p> <p>2 A. -- according to this.</p> <p>3 Q. Did -- do you recall at this</p> <p>4 meeting like -- do you recall if at this</p> <p>5 meeting you felt like Ethicon and physicians</p> <p>6 felt like you needed to do damage control to</p> <p>7 address the 2008 public health notification?</p> <p>8 A. I don't recall.</p> <p>9 Q. Would you agree that if the</p> <p>10 fear of being named in a lawsuit prevents</p> <p>11 someone from using a product that is unsafe,</p> <p>12 that that's a good thing?</p> <p>13 A. Can you repeat that for me,</p> <p>14 please.</p> <p>15 Q. Would you agree that if the</p> <p>16 fear of being named in lawsuits prevents</p> <p>17 someone from selling a product that is</p> <p>18 unsafe, that that's a good thing?</p> <p>19 A. No, I don't think that's a good</p> <p>20 thing.</p> <p>21 Q. Well, you'd agree that asbestos</p> <p>22 in this country is generally no longer being</p> <p>23 sold, right?</p> <p>24 A. I don't know anything about</p>	<p>1 asbestos fibers can cause lung cancer, but</p> <p>2 beyond that, I really don't have an opinion.</p> <p>3 Q. So if fear of being sued</p> <p>4 prevented a company from putting out an</p> <p>5 asbestos product that could be inhaled into</p> <p>6 the body and that was the only thing that</p> <p>7 kept that company from putting that product</p> <p>8 out, do you believe that would be a bad</p> <p>9 thing?</p> <p>10 A. I don't know. I don't have an</p> <p>11 opinion about that.</p> <p>12 Q. If you go to the last bullet</p> <p>13 point, "Recommendations to Group: Clinical</p> <p>14 Data," it says, "Do studies on ISD" -- which</p> <p>15 I assume is intrinsic sphincter deficiency --</p> <p>16 "smokers, obesity and safety." Do you see</p> <p>17 that?</p> <p>18 A. Yes.</p> <p>19 Q. So at this time in 2009, one of</p> <p>20 the recommendations to Ethicon, that this</p> <p>21 group that you participated in, was that</p> <p>22 Ethicon needed more data on safety.</p> <p>23 A. What it says here is they --</p> <p>24 the recommendation was to do studies on</p>
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<p>1 asbestos.</p> <p>2 Q. You don't know anything about</p> <p>3 asbestos?</p> <p>4 A. No.</p> <p>5 Q. You don't know whether -- as a</p> <p>6 physician, whether or not asbestos causes</p> <p>7 cancer and is hazardous to human health?</p> <p>8 A. I do know that it causes</p> <p>9 mesothelioma, but I don't know about the</p> <p>10 asbestos product line or market or lawsuits</p> <p>11 or anything like that.</p> <p>12 Q. Would you agree that asbestos</p> <p>13 should never be used in a medical device?</p> <p>14 A. I don't know why it would be</p> <p>15 used in a medical device.</p> <p>16 Q. That's not my question. Would</p> <p>17 you agree that asbestos should never be used</p> <p>18 in a medical device?</p> <p>19 A. I don't know. I don't know</p> <p>20 enough about it.</p> <p>21 Q. You don't know whether or not</p> <p>22 it's harmful for asbestos to be placed in</p> <p>23 continuous contact with the human body?</p> <p>24 A. Well, I know that inhalation of</p>	<p>1 safety. I don't -- that's all I can say</p> <p>2 about it.</p> <p>3 Q. One of the other</p> <p>4 recommendations was that Ethicon get more</p> <p>5 data on how the mesh could be used in people</p> <p>6 who were obese or smoked.</p> <p>7 A. That's what it says here.</p> <p>8 Q. Does that indicate that at this</p> <p>9 time there wasn't sufficient data on how the</p> <p>10 mesh behaved in individuals who were obese or</p> <p>11 smoked?</p> <p>12 A. I don't know. I would have to</p> <p>13 look at what studies were available at that</p> <p>14 time in 2008.</p> <p>15 MR. FAES: William, I could go</p> <p>16 on, but I think I'm at about my</p> <p>17 two-hour limit.</p> <p>18 MR. GAGE: Okay. I guess I do</p> <p>19 my follow-up?</p> <p>20 MR. FAES: Yeah.</p> <p>21 MR. GAGE: Let me take just a</p> <p>22 little break.</p> <p>23 (Recess Taken From 10:41 a.m.</p> <p>24 To 10:53 a.m.)</p>

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<p style="text-align: right;">Page 255</p> <p>1 EXAMINATION</p> <p>2 BY MR. GAGE:</p> <p>3 Q. Dr. Pramudji, my name is</p> <p>4 William Gage, and I've got just a couple of</p> <p>5 questions for you. You were asked, I believe</p> <p>6 yesterday, some questions about the Prosima</p> <p>7 IFU. Do you recall that?</p> <p>8 A. Yes.</p> <p>9 Q. And in particular, some of the</p> <p>10 questions related to whether the IFU -- the</p> <p>11 Prosima IFU referenced anything about</p> <p>12 stage IV pelvic organ prolapse. Do you</p> <p>13 recall those questions?</p> <p>14 A. Yes.</p> <p>15 Q. Do you recall generally what</p> <p>16 the question that was posed to you was?</p> <p>17 A. I think it was the indications</p> <p>18 for the Prosima for what stage it's</p> <p>19 indicated.</p> <p>20 Q. And were you asked whether the</p> <p>21 Prosima IFU made any references with regard</p> <p>22 to stage IV?</p> <p>23 A. I believe so.</p> <p>24 Q. And do you remember what your</p>	<p style="text-align: right;">Page 257</p> <p>1 asked about it had forgotten?</p> <p>2 A. Yes, I had forgotten about</p> <p>3 that.</p> <p>4 Q. Doctor, you were asked a number</p> <p>5 of questions yesterday and perhaps some today</p> <p>6 about certain opinions that you have where</p> <p>7 you disagree with the FDA. Do you recall</p> <p>8 those questions?</p> <p>9 A. Yes.</p> <p>10 Q. Are you alone among pelvic</p> <p>11 floor surgeons in disagreeing with the FDA on</p> <p>12 certain issues related to pelvic organ</p> <p>13 prolapse mesh?</p> <p>14 A. No. As a matter of fact, there</p> <p>15 is a network of dozens of pelvic surgeons who</p> <p>16 have even issued statements disagreeing with</p> <p>17 the FDA.</p> <p>18 Q. And at a high level, what are</p> <p>19 those disagreements with regard to pelvic</p> <p>20 organ prolapse mesh?</p> <p>21 A. The disagreements are that --</p> <p>22 the statement that the complications are not</p> <p>23 rare, because the literature and the personal</p> <p>24 use indicates that the complications are</p>
<p style="text-align: right;">Page 256</p> <p>1 answer was?</p> <p>2 A. I did not think it made a</p> <p>3 reference to that.</p> <p>4 Q. Okay. I'm handing you the</p> <p>5 Prosima IFU that today has been marked as</p> <p>6 Exhibit 11, and I'm showing you the warnings</p> <p>7 and precautions section of the IFU. Do you</p> <p>8 see that?</p> <p>9 A. Yes.</p> <p>10 Q. And the second bullet under</p> <p>11 "Warnings and Precautions" says, "Use of the</p> <p>12 Gynecare Prosima System has not been fully</p> <p>13 evaluated in patients with Stage IV pelvic</p> <p>14 organ prolapse. Therefore its use in these</p> <p>15 patients is not recommended."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. What is the significance, if</p> <p>19 any, of that statement to your answers</p> <p>20 yesterday about stage IV and the Prosima IFU?</p> <p>21 A. Yes. So the IFU indicates that</p> <p>22 it is not recommended for stage IV prolapse.</p> <p>23 Q. And is that something you read</p> <p>24 that had just -- yesterday when you were</p>	<p style="text-align: right;">Page 258</p> <p>1 rare. And also that the benefits of mesh are</p> <p>2 in question; whereas studies, particularly</p> <p>3 for a cystocele repair, indicate that there</p> <p>4 is a definite benefit in efficacy using mesh</p> <p>5 implants.</p> <p>6 Q. You have been asked some</p> <p>7 questions yesterday and today about whether</p> <p>8 the mesh in Prosima, Prolift and Gynemesh PS</p> <p>9 was cut with a machine or cut with a laser.</p> <p>10 Do you recall those questions?</p> <p>11 A. Yes.</p> <p>12 Q. What is the clinical</p> <p>13 significance, if any, as to whether the mesh</p> <p>14 in those three devices is cut by a machine</p> <p>15 with a blade or cut by a laser?</p> <p>16 A. There's really no clinical</p> <p>17 impact one way or another as far as efficacy</p> <p>18 or complications. And particularly, as I</p> <p>19 mentioned earlier, most surgeons are going to</p> <p>20 trim the edges of the mesh to some degree or</p> <p>21 another, usually quite extensively, and</p> <p>22 therefore the edges effectively all become</p> <p>23 scissor cut when they're implanted.</p> <p>24 Q. Doctor, how long have you been</p>

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<p style="text-align: right;">Page 259</p> <p>1 working with Ethicon on the pelvic organ 2 prolapse mesh litigation? Do you recall when 3 you were first retained? 4 A. I think it was three years ago, 5 if I remember correctly. 6 Q. Is it fair to say that you've 7 reviewed a lot of materials going back to 8 that date? 9 A. Yes. 10 Q. And some of that would include 11 company documents? 12 A. That's correct. 13 Q. And would you have also 14 reviewed patient medical records? 15 A. Yes. 16 Q. You testified earlier that you 17 were unaware that the indications section of 18 the Gynemesh PS IFU had been changed 19 recently. Do you recall that? 20 A. Yes. 21 Q. Is it possible that that was a 22 fact that you knew from your prior and 23 earlier work on the pelvic organ prolapse 24 litigation, but it is something that when you</p>	<p style="text-align: right;">Page 261</p> <p>1 grade IV prolapse. 2 A. That's correct. 3 Q. You said that there are other 4 pelvic floor surgeons who disagree with the 5 FDA and that there are organizations of those 6 physicians. What are those organizations? 7 A. I think it's called the Pelvic 8 Floor Mesh Network. 9 Q. Are you a member of that 10 organization? 11 A. I signed on to the 12 communication. It's not -- I don't know that 13 it's an organization per se, or if it was 14 just a consortium of surgeons that were all 15 of like mind as far as pelvic surgery. 16 Q. Do you know how many surgeons 17 belong to that organization? 18 A. Seems like there were dozens on 19 the e-mails. But I don't know an exact 20 number. 21 Q. You don't know a number -- 22 A. No. 23 Q. -- as you sit here today? So 24 it's possible that this is an organization of</p>
<p style="text-align: right;">Page 260</p> <p>1 were asked that question you had forgotten? 2 A. Yes, that's entirely possible, 3 with all the voluminous information I've 4 tried to absorb. 5 MR. GAGE: That's all I have. 6 MR. FAES: Just a couple of 7 questions, Doctor. 8 FURTHER EXAMINATION 9 BY MR. FAES: 10 Q. With regard to the Prosima IFU, 11 you'd agree that in the indications-for-use 12 section, there's nothing in the IFU that says 13 that the Prosima should only be used for 14 grades II and III prolapse, correct? 15 A. In that section, that is 16 correct. 17 Q. You'd agree that there's 18 nothing in that section that informs 19 physicians that it shouldn't be used for a 20 grade IV prolapse, correct? 21 A. That's correct. 22 Q. In fact, there's no 23 contraindication in this section informing 24 physicians that it's not indicated for</p>	<p style="text-align: right;">Page 262</p> <p>1 outlier physicians who disagree with the FDA 2 since you don't know the number of physicians 3 that belong to this group? 4 A. No, these were mainstream 5 surgeons, prolific users that had a lot of 6 experience and had -- 7 Q. How do you know that there're 8 mainstream users who are other members of 9 this organization? 10 A. Well, in particular I remember 11 Dr. Lucente, Dr. Supulveda. That's all I can 12 remember off the top of my head. But it was 13 people that I was familiar with that -- 14 professors, people that had a lot of 15 experience with pelvic mesh that had seen how 16 it actually behaved in patients. 17 Q. You know that Dr. Supulveda is 18 an expert in mesh litigation, correct? 19 A. Yes. 20 Q. You know that Dr. Lucente is an 21 expert in mesh litigation, correct? 22 A. I didn't know about that. 23 Q. You know that Dr. Lucente has 24 received over a million dollars from Ethicon</p>



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<p style="text-align: right;">Page 263</p> <p>1 for his consulting work related to mesh, 2 correct? 3 A. I don't know about that. 4 MR. GAGE: Object to form. 5 BY MR. FAES: 6 Q. If those -- if that's true, 7 that Dr. Lucente has received over a million 8 dollars, wouldn't that present a conflict for 9 him when he had a financial incentive to 10 support the continued use of mesh? 11 A. No. I don't see that as a 12 major conflict. 13 Q. You don't think a person who's 14 made over a million dollars off of mesh 15 consulting would have an incentive to have 16 the use of mesh continue? 17 A. You know, I think it's fair for 18 physicians to be compensated for their time. 19 You want people that use it a lot to be your 20 consultant and to train other people and they 21 need to be compensated. So I don't know -- I 22 don't see how you can avoid that issue. I 23 don't -- and I can't speak to his motivation. 24 MR. FAES: I'm going to object</p>	<p style="text-align: right;">Page 265</p> <p>1 A. No, I would -- I would say -- I 2 would say that's not rare. 3 Q. Would you say an event that -- 4 an adverse event that occurs in one out of 5 five patients is common? 6 A. I wouldn't say common. 7 Q. But you would agree that it's 8 not rare? 9 A. Yeah, I would not call that 10 rare. 11 Q. You state that you know of -- 12 you don't believe there's a clinical impact 13 between the use of laser cut or mechanically 14 cut mesh. Are you aware of any clinical 15 study that specifically looked at the safety 16 as a primary end point between laser cut and 17 mechanically cut surgical mesh? 18 A. Not that I can think of right 19 now. 20 Q. Do you believe that you at one 21 point knew that the indications for use for 22 the Gynemesh PS had changed in 2013 and just 23 forgot? 24 A. Yes. I just forgot about that.</p>
<p style="text-align: right;">Page 264</p> <p>1 and move to strike as nonresponsive. 2 I'm going to re-ask it because I don't 3 think you've answered my question. 4 A. Sorry. 5 BY MR. FAES: 6 Q. Do you think a person who's 7 made over a million dollars off of mesh 8 consulting would have an incentive to see the 9 use of mesh continue? 10 A. I don't know. 11 Q. Are there any other 12 organizations you're aware of that disagree 13 with the FDA's stance on pelvic mesh other 14 than the Pelvic Floor Mesh Network? 15 A. Not that I can think of right 16 as I sit here. 17 Q. You specifically said that one 18 of the things that the FDA said that this 19 organization disagrees with is that 20 complications associated with pelvic organ 21 prolapse mesh are not rare; is that correct? 22 A. That's correct. 23 Q. Do you consider an event that 24 occurs in one out of five people to be rare?</p>	<p style="text-align: right;">Page 266</p> <p>1 Q. Do you feel like that's an 2 important fact that you should know in 3 rendering an opinion about whether or not the 4 Gynemesh PS, Prolift and Prolene Soft is 5 defective? 6 A. No, I don't think it matters 7 one way or another. 8 MR. FAES: That's all the 9 questions I have. 10 MR. GAGE: I don't have any 11 follow-up. 12 (Deposition Concluded At 13 11:06 a.m.) 14 --o0o-- 15 16 17 18 19 20 21 22 23 24</p>

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<p>1 CERTIFICATE</p> <p>2 I, MICHEAL A. JOHNSON, Registered</p> <p>3 Diplomat Reporter, Certified Realtime</p> <p>4 Reporter, Certified Court Reporter and Notary</p> <p>5 Public, do hereby certify that prior to the</p> <p>6 commencement of the examination, CHRISTINA</p> <p>7 PRAMUDJI, M.D. was duly sworn by me to</p> <p>8 testify to the truth, the whole truth and</p> <p>9 nothing but the truth.</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the</p> <p>12 testimony as taken stenographically by and</p> <p>13 before me at the time, place and on the date</p> <p>14 hereinbefore set forth, to the best of my</p> <p>15 ability.</p> <p>16 I DO FURTHER CERTIFY that pursuant</p> <p>17 to FRCP Rule 30, signature of the witness was</p> <p>18 not requested by the witness or other party</p> <p>19 before the conclusion of the deposition.</p> <p>20 I DO FURTHER CERTIFY that I am</p> <p>21 neither a relative nor employee nor attorney</p> <p>22 nor counsel of any of the parties to this</p> <p>23 action, and that I am neither a relative nor</p> <p>24 employee of such attorney or counsel, and</p> <p>that I am not financially interested in the</p> <p>action.</p> <p>MICHEAL A. JOHNSON, RDR, CRR</p> <p>NCRA Registered Diplomat Reporter</p> <p>NCRA Certified Realtime Reporter</p> <p>Certified Court Reporter</p> <p>Notary Public in and for the</p> <p>State of Texas</p> <p>My Commission Expires: 8/8/2016</p> <p>Dated: March 24, 2016</p>	<p>1 ERRATA</p> <p>2 PAGE LINE CHANGE</p> <p>3</p> <p>4 REASON: _____</p> <p>5</p> <p>6 REASON: _____</p> <p>7</p> <p>8 REASON: _____</p> <p>9</p> <p>10 REASON: _____</p> <p>11</p> <p>12 REASON: _____</p> <p>13</p> <p>14 REASON: _____</p> <p>15</p> <p>16 REASON: _____</p> <p>17</p> <p>18 REASON: _____</p> <p>19</p> <p>20 REASON: _____</p> <p>21</p> <p>22 REASON: _____</p> <p>23</p> <p>24 REASON: _____</p>
<p>Page 268</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it.</p> <p>10 You are signing same subject to</p> <p>11 the changes you have noted on the errata</p> <p>12 sheet, which will be attached to your</p> <p>13 deposition.</p> <p>14 It is imperative that you return</p> <p>15 the original errata sheet to the deposing</p> <p>16 attorney within thirty (30) days of receipt</p> <p>17 of the deposition transcript by you. If you</p> <p>18 fail to do so, the deposition transcript may</p> <p>19 be deemed to be accurate and may be used in</p> <p>20 court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 270</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3</p> <p>4 I, CHRISTINA PRAMUDJI, M.D., do</p> <p>5 hereby certify that I have read the foregoing</p> <p>6 pages and that the same is a correct</p> <p>7 transcription of the answers given by me to</p> <p>8 the questions therein propounded, except for</p> <p>9 the corrections or changes in form or</p> <p>10 substance, if any, noted in the attached</p> <p>11 Errata Sheet.</p> <p>12</p> <p>13 CHRISTINA PRAMUDJI, M.D. DATE</p> <p>14</p> <p>15 Subscribed and sworn to before me this</p> <p>16 _____ day of _____, 20 ____.</p> <p>17 My commission expires: _____</p> <p>18</p> <p>19</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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